



# Group versus Individual Treatment in the management of rotator cuff tendinopathy in primary care.

**A thesis submitted for the award of Master of Science**

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Submitted to the University of Limerick April 2021

## **ABSTRACT**

Shoulder pain is a common and disabling musculoskeletal disorder seen in Primary Care physiotherapy. Exercise-based treatment is effective for managing rotator cuff tendinopathy. Group-based and individual physiotherapy treatments have been found to have similar outcomes in terms of pain and disability in delivering exercise interventions for musculoskeletal disorders. Group treatment may be more resource efficient and result in decreased use of secondary care when compared to individual physiotherapy. Group participants have reported positive experiences of this format. There has been limited evidence comparing group versus individual treatment in the management of rotator cuff tendinopathy.

i) to investigate whether group exercise is as effective as multi-modal one-to-one physiotherapy using the Shoulder Pain and Disability Index (SPADI) to assess changes in pain and disability from baseline to 6 weeks, 12 weeks and 24 weeks. (Design: Randomised Controlled Trial)

ii) to explore participants' experiences of and preferences for both formats of treatment delivery. (Design : Qualitative Descriptive)

## **Methods**

The first study (presented in Chapters 2-4) is a two-arm, interventional, assessor-blinded, randomised trial. Patients with a history of lateral arm were recruited from the waiting list of a Primary Care Physiotherapy department. Participants were screened for presence of rotator cuff tendinopathy. Baseline measures of the SPADI, Quick Disability of the Arm, Shoulder and Hand (QuickDASH) and Constant-Murley Score (CMS) were administered by an independent assessor

blinded to group allocation. These measures plus the Patient Global Impression of Change (PGIC) were reassessed at 6 weeks, 12 weeks and 24 weeks. The individual treatment participants received their physiotherapy according to their therapist's discretion. The group intervention consisted of 12 sessions of a one-hour circuit-type exercise class.

## **Results**

69 eligible participants were recruited (n=35 group, n=34 individual treatment). Losses to follow-up and missing data were accounted for using an intention to treat analysis. Both groups achieved a statistically significant level of change from baseline in SPADI by 6 weeks. There was no statistically significant between-group difference at any follow up time-point (p=0.11 at 6 weeks, p=0.21 at 12 weeks & p=0.07 at 24 weeks) for the SPADI total. The QuickDASH and CMS show similar results. However, the SPADI pain showed a statistically significant difference in favour of the group at 6 weeks (p=0.03) and 24 weeks (p=0.02). Participants of the group also experienced a clinically significant improvement in SPADI earlier than the individual treatment participants. A higher proportion of group participants reported their shoulder condition as "improved" at 6 weeks and 24 weeks.

## **Qualitative study**

The second study in this thesis (Chapter 5) is a qualitative descriptive study exploring participants' experiences of and preferences for both formats of treatment delivery. Semi-structured interviews were conducted with RCT participants, five from group exercise, five from individual treatment. The transcribed data were analysed using thematic analysis.

Three themes were identified – “What patients value from treatment”, “Engagement with exercise during and after treatment” and “Characteristics of a successful outcome”.

**Key findings arising from this thesis:**

- The RCT found that there was no difference in outcome for participants with rotator cuff tendinopathy managed either with group or individual physiotherapy
- The results of the qualitative study show a satisfaction with both formats of treatment delivery, the value of support from therapists and other patients and positive beliefs about the effectiveness and value of exercise for rotator cuff tendinopathy.
- Education and advice on managing the condition was deemed important and participants from both groups developed a confidence in self-management.
- This thesis provides support for group-based exercise for rotator cuff tendinopathy in a Primary Care setting as an effective alternative to individual treatment. A larger multi-centre trial is required to increase the generalisability of these results.

## **DECLARATION**

I declare that this thesis is entirely my own work and that it has not been submitted as an exercise for a degree at this or any other University.

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## ACKNOWLEDGEMENTS

I would like to thank the following people:

My colleagues and co-collaborators Karina Teahan and Sinead Lynch for coming up with the idea of conducting an RCT and the work involved in designing and carrying out the project. I would also like to thank them for their generosity in allowing me to use the data to pursue this masters.

Noreen Walsh for her guidance in designing the RCT, endless hours of assessments and for encouraging me to do the masters.

My primary supervisor, Dr Karen McCreesh, for her patience, enthusiasm for the study, expertise and approachability.

My secondary supervisors, Dr Ann-Marie Morrissey and Dr Rose Galvin, for their contributions, knowledge, encouragement and adding more perspectives.

Aoife Collins and Linda Armstrong for carrying out the individual treatment intervention.

Dr Mark Phelan for taking an interest in the project and his help with the ethics applications.

Sandra Keyes for lending the wisdom of her experience.

Our managers, Liz O'Sullivan and Patricia Morrisroe, for allowing us the freedom and flexibility in our work to pursue this project.

To my family for their support, in particular my sister Fiona for putting me up during my convalescence.

*for my mother*

*the wind beneath my wings*

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# CHAPTER 1 Introduction

## 1.1 Incidence of rotator cuff tendinopathy

Shoulder pain is the third most common musculoskeletal condition referred to primary care physiotherapy after back and knee pain (Kooijman *et al.* 2013). Rotator cuff (RC) tendinopathy is the most common shoulder condition for which patients consult a doctor (Tekavec *et al.* 2012) with an estimated incidence of 0.3-5.5% (point prevalence of 2.4%- 21% across all age groups and annual prevalence 0.5-7.4%) (Littlewood *et al.* 2013b). Shoulder pain has a significant impact on an individual's perception of general health that rates in severity with conditions such as myocardial infarction, congestive cardiac failure and clinical depression (Gartsman *et al.* 1998). Sleep, activities of daily living and leisure can be severely affected (Lowe *et al.* 2014) and more than 40% of people with shoulder pain continue to have recurrent problems after one year (Winters *et al.* 1999; Kuijpers *et al.* 2004). This results in significant health care costs at primary and secondary care level (Virta *et al.* 2012).

## 1.2 Terminology

The term rotator cuff tendinopathy is broad and may include various conditions including subacromial impingement, bursitis, RC tears and even acromio-clavicular joint (ACJ) osteoarthritis (Littlewood *et al.* 2013a, Wong *et al.* 2020). It incorporates both rotator cuff tendinitis and tendinosis. Tendinitis signifies a condition associated with inflammation. Tendinosis refers to the degenerative changes seen in tendons. The term subacromial impingement syndrome implies tendon compression within the subacromial space via an extrinsic mechanism. This label is still frequently used.

However, (Lewis 2016) argues that the term is unhelpful and misleading as it assumes an extrinsic origin and proposed the term rotator cuff related shoulder pain (RCRSP) as an umbrella term which does not allude to the causative mechanism. In this thesis, RC tendinopathy will be used as it is a term indicating tendon pain and impaired function (Fredberg and Stengaard-Pedersen 2008) and does not make any presumptions about the aetiology or stage of the condition.

### **1.3 Anatomy**

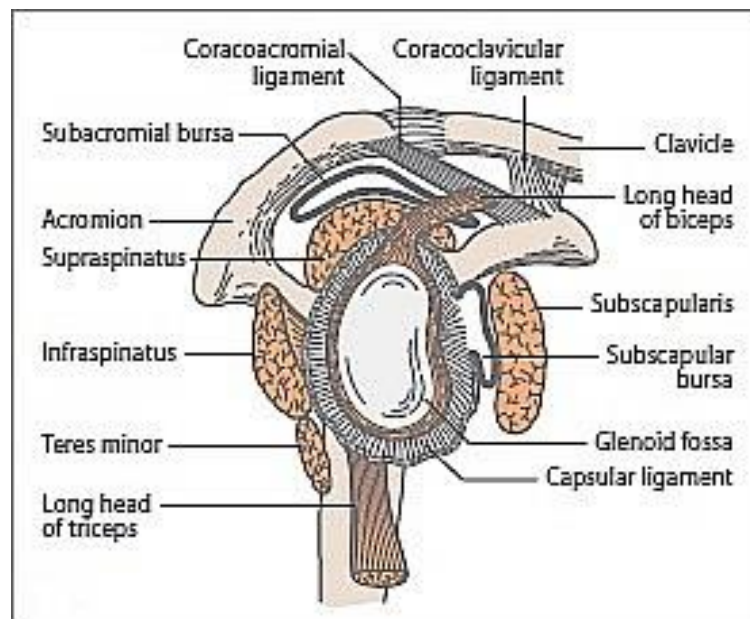
The shoulder joint is an exceptionally mobile joint with large ranges of motion in all movement planes (Halder *et al.* 2000). The RC consists of the supraspinatus, infraspinatus, subscapularis and teres minor muscles. The tendons blend and interdigitate to form a cuff or sleeve help to centre the head of humerus (HOH) in the glenoid fossa, such that it is not possible to isolate one muscle using resisted tests (Camargo *et al.* 2014). The advantage of this is that if small tears occur, even full-thickness tears, the cuff can continue to function (Lewis 2016). There is an area of decreased vascularity in the tendon of the supraspinatus known as the critical zone located close to the insertion of the supraspinatus tendon on the greater tuberosity of the humerus. Degenerative changes and tears are commonly seen at this site. (Huri *et al.* 2019)

The shallow glenoid fossa and relatively large humeral head of the gleno-humeral joint means that it is inherently unstable (Halder *et al.* 2000). It is dependent on a functioning rotator cuff not only for stability but to produce movement. The rotator cuff contributes to joint stability by centring the head of the humerus on the glenoid. Wattanaprakornkul *et al.* (2011) demonstrated that the rotator cuff is activated to oppose anterior-posterior humeral head translation caused by the large torque-producing muscles. It is also reliant on precise neuro-muscular control of the scapula-



thoracic muscles to orientate the glenoid to articulate optimally with the head of the humerus (HOH) and to provide a stable platform in the form of a steady scapula (Schachter *et al.* 2010).

The ACJ is prone to degenerative changes which increase with age. The sub-acromial space is bounded the coraco-acromial arch which consists of the coraco-acromial ligament (CAL) and the acromion superiorly and the gleno-humeral joint inferiorly. The contents of the sub-acromial space include the sub-acromial bursa, the superior part of the cuff (tendons of the posterior cuff) and the GH joint capsule (**Figure 1**). The CAL is prone to developing osteophytes at its acromial insertion, these may be the consequence of poor humeral head control (due to a poorly functioning RC) as opposed to the cause of sub-acromial impingement as was previously supposed (Lewis *et al.* 2015).



**Figure 1** Rotator cuff tendons and subacromial space (gpnotebook n.d.)

## 1.4 Tendon Structure

Tendons exhibit a rate low of metabolic activity and slow rate of cell turnover (Mersmann *et al.* 2017). They are composed of collagen producing cells, tenocytes, in a matrix of ground substance comprising of collagen fibrils which are connected by crosslinks, proteoglycans, glycoproteins, glycosaminoglycans and water (Camargo *et al.* 2014). Type I collagen is found in healthy tendons and has a higher elasticity than type II or III collagen which is more fibrotic and found in cartilage. This is what gives tendons their tensile strength. Tendons cope well with tensile loads but when load exceeds capacity tissue failure will occur. Like any other tissue in the body, tendons respond to stimuli by remodelling (Maffulli and Longo 2008). It is accepted that the rate of tendon remodelling is slow. Estimated to be at least two months slower than muscle. (Mersmann *et al.* 2017)

## 1.5 Mechanisms of RC tendinopathy

The aetiology of rotator cuff tendinopathy is multifactorial and may consist of a complex of conditions involving intrinsic, extrinsic and psychosocial factors interacting with altered pain processing, peripheral and central sensitisation (**Figure 2**) (Seitz *et al.* 2011; McCreesh and Lewis 2013; Braman *et al.* 2014; Wong *et al.* 2020)

### 1.5.1 Extrinsic mechanisms

Neer (1972) proposed the impingement model, this involves extrinsic mechanisms causing compression and shearing to the sub-acromial structures by a combination of bony variations such as the hooked acromion and bony spurs associated with the CAL and ACJ. This has been a popular theory amongst physiotherapists and surgeons (Lewis 2016), but it does not account for all sources of RC tendinopathy such as the

fact that more commonly degenerative changes of the supraspinatus tendon are seen on the articular side rather than the bursal side and there is evidence of intra-tendinous tears (Fukuda 2003). More recently, an additional theory for extrinsic factors put forward was that of internal impingement which accounts for structural changes occurring on the articular side of the tendons (Seitz *et al.* 2011). The mechanism of injury is thought to be pinching or trapping of the tendon between the HOH and the superior lip of the glenoid as a result of poor RC control (centring) or poor scapula-humeral rhythm.

### ***1.5.2 Intrinsic mechanisms***

Intrinsic mechanisms include processes occurring within the tendon and other related metabolic processes (Seitz *et al.* 2011). It is influenced by systemic illnesses such as diabetes, smoking, obesity, certain medications and stress shielding. Obesity leads to fatty infiltration of the tendon which weakens it. Systemic illnesses, medications and smoking impact on tendon health (Lewis *et al.* 2015; Lewis 2016). In healthy tendons, homeostasis occurs where there is a balance of anabolism and catabolism. Catabolism refers to the destruction of cells. Normally this is matched by the production of new cells, anabolism, stimulated by tissue loading or tensile stresses. However, in a stress-shielded tendon when the tendon is not exposed to adequate loading the net result is an overall loss of collagen leading to a decrease in tensile strength and elasticity (Cook and Purdam 2009). Ageing and genetic factors also play a role, but they are not modifiable risk factors. Some of the modifiable risk factors are lifestyle-related consequently education will have a vital role in the management of the condition.

### ***1.5.3 Inflammation***

There has been debate in the literature over whether inflammation plays a part in the patho-aetiology of the condition. The failure to detect inflammatory cells in some histological studies has led researchers to conclude that inflammation is not associated with the condition and therefore tendinitis is not appropriate (Alfredson and Lorentzon 2002; Khan *et al.* 2002). However, the response to corticosteroids observed in terms of reduction in pain and decrease in tendon thickness is similar to that seen with other inflammatory conditions such as rheumatoid arthritis, implying that there must be some inflammation present (Fredberg and Stengaard-Pedersen 2008).

### ***1.5.4 Continuum model***

Injured or diseased tendon is broadly classified into two categories – reactive and degenerative. Reactive tendinopathy is characterised by painful tendons where there is an increase in cell activity but essentially, they are structurally normal. Degenerative tendons, on the other hand, demonstrate disorganisation of the matrix, areas of acellularity due to cell death, neovascular infiltrates (angiogenesis) and few intact collagen fibres (Fredberg and Stengaard-Pedersen 2008; Cook and Purdam 2009). Cook and Purdam (2009) put forward the continuum model which describes different stages of tendon pathology (reactive, disrepair or failed healing stage and degenerative) based on structural changes. It was suggested that loading programmes be tailored to the stage of pathology with reactive tendinopathies requiring offloading to allow natural healing to occur but degenerative tendons requiring a loading stimulus to remodel (Cook *et al.* 2009). Tendon overload, either as a result of repetitive strain in an athlete or a consequence of an unaccustomed load to a stress shielded tendon, is

proposed to be the cause of most tendon injury (Fredberg and Stengaard-Pedersen 2008; Cook and Purdam 2009; Mersmann *et al.* 2017)

McCreesh & Lewis (2013) synthesised primary research evidence examining the validity of the continuum model. While research into pathology supported the model, the evidence was difficult to evaluate as few studies use homogeneous samples and they concluded that heterogeneous study populations may account for the wash-out effect of targeted interventions in some studies. It was recommended by McCreesh and Lewis (2013) that the continuum model should be expanded to consider all mechanisms of injury - intrinsic, extrinsic and occupational factors as well as recognising the role of psychosocial factors and the potential contribution of central sensitisation to the chronicity of tendinopathy.

The original continuum model suggested that management may be optimised by tailoring interventions to the stage of pathology and targeting cell activation to produce collagen and restructure the matrix (Cook and Purdam 2009). Cook *et al.* (2016) revisited the model and considered that the effect of load on tendon structure may vary depending on intrinsic factors. They also conceded that targeting tendon structure is ineffective as pathology has limited capacity to reverse and that instead of trying to change structure, treatment should aim to build load capacity in the aligned portion of the tendon using the analogy of a doughnut recommended “treating the doughnut, not the hole”.

Despite extensive theoretical modelling and research into the structural pathology, the patho-aetiology of rotator cuff tendinopathy is not fully understood (Lewis 2009) . As with most other musculoskeletal conditions there is a weak relationship between

pathology and symptoms and the source of pain in tendinopathy is not clear (Cook *et al.* 2016). Therefore, a reliance on tissue-based pathology is not likely to fully explain the condition.

### ***1.5.5 Central and Peripheral Sensitisation***

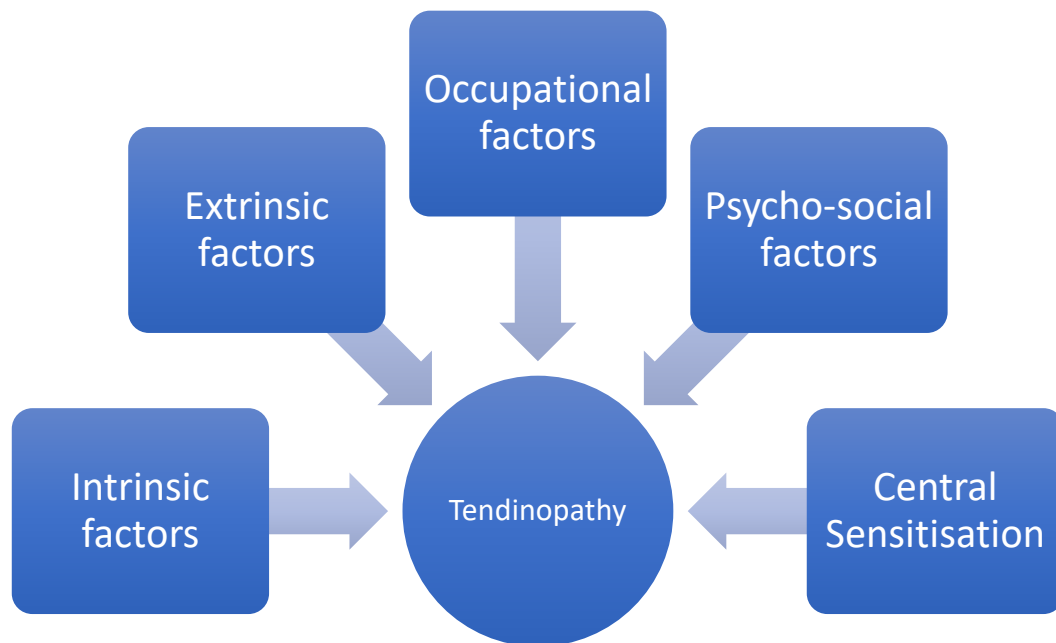
There is evidence that central and peripheral sensitisation are implicated in persisting pain states such as chronic whiplash, low back pain and fibromyalgia (Plinsinga *et al.* 2015). Altered pain processing and modulated output of the central nervous system (CNS), rather than just peripheral nociception in response to tissue damage, may offer an explanation for persisting pain in RC tendinopathy (Littlewood *et al.* 2013). Pressure (mechanical) and thermal pain thresholds are used to test for presence of peripheral and central sensitivity. A systematic review by Plinsinga *et al.* (2015) reported evidence of mechanical hyperalgesia locally and distal to the involved tendon and cold hyperalgesia in affected and unaffected sides in patients with upper limb tendinopathy. There was also evidence of altered central processing with loss of inhibitory mechanisms such as exercise induced analgesia (Plinsinga *et al.* 2015). Generalised mechanical hyperalgesia, allodynia and impaired pain modulation has been in shoulder pain patients indicating the involvement of the CNS. (Borstad and Woeste 2015; Noten *et al.* 2017).

The findings obtained were not homogenous in the trials reviewed which means that neither peripheral nor central processes predominate and suggests that patients with similar clinical presentations may not have uniform pain processes driving their symptoms. This could explain why some patients fail to recover after treatments which are focussed on local tissue pathology (Noten *et al.* 2017). Plinsinga *et al.* (2015) also noted that centrally mediated pain could involve psychosocial and behavioural factors.

### ***1.5.6 Psychosocial factors***

Emerging research is highlighting the influence of psychosocial factors in rotator cuff tendinopathy. Qualitative research into the experience of people with shoulder pain revealed that shoulder pain affects all areas of life with people with shoulder pain experiencing emotional distress - frustration, anxiety, depression and hidden suffering (Gillespie *et al.* 2017; Page *et al.* 2019). A systematic review by Wong *et al.* (2020) investigating the prevalence of psychological factors in patients with rotator cuff tendinopathy found that one quarter of patients report anxiety and depression and 70-90% report sleep disturbance and insomnia

Wong established that a range of psychological factors are associated with patient reported pain, disability and quality of life in chronic shoulder pain patients (Wolfensberger *et al.* 2016; Wylie *et al.* 2016; Wong *et al.* 2020).



**Figure 2** *Multifactorial nature of rotator cuff tendinopathy*

## 1.6 Diagnosis & Assessment

RC tendinopathy is characterised by relative preservation of gleno-humeral range of movement and pain on active movements, particularly overhead movements, or loading, often with little or no resting pain (Lewis *et al.* 2015). The difficulty with diagnosing RC tendinopathy is that objective signs are not always consistent, with special orthopaedic tests demonstrating poor specificity (Hegedus *et al.* 2012). Even expert clinicians can fail to consistently reproduce some signs (Fredberg and Stengaard-Pedersen 2008). It is impossible isolate the rotator cuff from other structures



around the shoulder, much less to isolate distinct parts of the rotator cuff because of the blending of the tendons prior to insertion to the greater tubercle of the humerus (Lewis 2016). While imaging, and particularly ultrasound, can detect structural changes (Fredberg and Stengaard-Pedersen 2008; McCreesh and Lewis 2013), it is not a reference standard. Significant structural changes, even partial and full thickness tears, can be completely asymptomatic. These are seen more commonly with increasing age (Minagawa *et al.* 2013). It has also been observed that substantial structural changes can occur in elite throwing athletes with no effect on function or evidence of pain (Lewis *et al.* 2015; Lewis 2016).

A comprehensive assessment should consist of a thorough history-taking with attention to lifestyle factors, current activity levels, functional restrictions, assessment of psychosocial factors - including the impact of the symptoms on the individual, his or her beliefs and expectations and other relevant psychosocial factors, co-morbidities, risk factors (age, obesity, diabetes and overhead activities), changes in loading history, medications and red flags (Lewis 2016; Lin *et al.* 2020; Salamh and Lewis 2020). Objective assessment should include an evaluation of active and passive range of movement of the shoulder noting the ranges of rotation and the presence of a painful arc on abduction. It should also include resisted tests of the rotator cuff looking for reproduction of pain and weakness and, where there is a suspicion of pain of spinal origin, an examination of spinal range, palpation, combined movements, neuro-integrity and neural tensioning tests. Finally, special orthopaedic impingement tests may be used to help confirm a hypothesis formed by the preceding examination. (Petty and Moore 2011; Lewis 2016)

### ***1.6.1 Special Orthopaedic Tests***

There are many special orthopaedic tests for the shoulder which may be used in the diagnosis or screening for RC tendinopathy. These include impingement tests (Neer, Hawkins-Kennedy, Cross body test, painful arc) and RC tests (empty can or Jobe's test, the external rotation/infraspinatus test, drop arm test, belly press and lift off test). Some of these tests work by placing a tensile load on the tendon, some create a compressive load on subacromial structures which include the subacromial bursa and the supraspinatus tendon (Michener *et al.* 2009).

Diagnostic accuracy refers to the ability of a test to differentiate between the presence and absence of the condition under investigation. Measures of diagnostic accuracy include sensitivity and specificity, predictive values, likelihood ratios, the area under the receiver operating curve (ROC) and diagnostic odds ratios (Šimundić 2009). Several studies have investigated the diagnostic accuracy of special orthopaedic tests to identify RC tendinopathy (MacDonald *et al.* 2000; Holtby and Razmjou 2004; Park *et al.* 2005). However, some of these studies have serious methodological flaws such as a lack of blinding of the examiner and use of an unsatisfactory reference standard i.e. imaging rather than surgical findings (Michener *et al.* 2009).

In the context of this thesis, sensitivity is defined as the proportion of people with RC tendinopathy who will have a positive clinical test result and is calculated only from those with the condition. Specificity is the ability of a test to correctly identify when the condition is absent and is calculated only from those without the condition. Both are reported from 0-100%. Likelihood ratios (LR+ and LR-) are calculated from sensitivity and specificity values and take into account subjects with and without the disease. Both LR+ and LR- are used to calculate post-test probabilities. A strong test

or cluster of tests (with post-test probabilities close to 100) should have the ability to rule a condition in when positive and a lower LR- to rule it out when negative (with post-test probabilities close to 0). (Hegedus *et al.* 2015).

A well designed, prospective cohort study by Michener *et al.* (2009) which included blinded examiners and compared examination results to arthroscopic findings sought to establish the diagnostic accuracy and inter-rater reliability of 5 tests (painful arc, external rotation test, empty can test, Hawkins-Kennedy and Neer test) commonly used to screen for RC tendinopathy.

<b>Neer test:</b> the examiner fixes the scapula with a downward pressure on the top of the shoulder and flexes the shoulder to full elevation with overpressure, compressing the bursa and the supraspinatus. A positive test reproduces pain at the top of the shoulder.
<b>Hawkins-Kennedy test:</b> while fixing the scapula with a downward pressure on the shoulder, the examiner passively flexes the gleno-humeral joint to 90 degrees and internally rotates the shoulder a positive test reproduces pain at the top of the shoulder.
<b>Painful arc</b> involves active abduction of the shoulder. If pain is reproduced between 60-120 degrees of abduction this is deemed to be a positive test.
<b>Empty can test:</b> the shoulder is abducted to 90 degrees in the plane of the scapula it is the maximally internally rotated and the subject resists while the examiner exerts a downward pressure applied at the wrist. Reproduction of pain or weakness is a positive test.
<b>External rotation test:</b> the elbow is flexed to 90 degrees and keeping the arm by the subject's side the examiner exerts a medially directed force at the wrist while the subject resists. Reproduction of pain or weakness signifies a positive test.

Michener *et al.* (2009) also used linear regression analysis to identify the best cluster of tests to rule the condition in or out. Clustering of tests improves sensitivity and specificity and more accurately reflects the clinical reasoning process of experienced clinicians by coalescing a number of signs and symptoms (Hegedus *et al.* 2015). They found that no one test can rule the condition in or out, but the External Rotation test has the best sensitivity and LR+ ratio. It was also the most reliable. The Neer test was the most specific test but demonstrated poor reliability. Regarding clustering, positive findings on 3 of the 5 tests allows you to diagnose the condition with 80% accuracy whereas fewer than 3 positive tests can rule the condition out (Michener *et al.* 2009). However, subjects who were found to have rotator cuff tears were diagnosed as not having the condition, so had the tests been positive in these patients, they would have been classed as false positives. This may have underestimated the accuracy of the tests as we now consider both subacromial impingement syndrome and RC tears to be on the spectrum of RC tendinopathy. The results of the tests were compared with surgical findings but as discussed earlier there is a poor association between structural changes and symptoms and the surgical findings may not be the source of the symptoms. This casts doubt on the validity of using imaging or surgical findings to diagnose shoulder symptoms. Some authors have questioned the diagnostic usefulness of these tests and judged them to be simply non-specific pain provocation tests (Lewis 2016;Hegedus *et al.* 2017; Salamh and Lewis 2020). Nonetheless, in the absence of a reference standard for diagnosing rotator cuff tendinopathy the inclusion of these tests may serve merely to confirm to a clinical impression formulated in the context of the whole clinical picture.

## 1.7 Management

Management of RC tendinopathy represents a significant challenge with 40% reporting ongoing pain and disability (Winters *et al.* 1999; Kuijpers *et al.* 2004). A range of management options are available including surgery and conservative treatment approaches.

### 1.7.1 Surgery

Surgical management of rotator cuff tendinopathy aims to address anatomical or structural causes of subacromial pain by the removal of structures encroaching on the subacromial space (acromioplasty, arthroscopic subacromial decompression (ASD), bursectomy) or the repair of tendon tears.

Research has shown while there are better outcomes with surgery in the short-term, medium to long-term outcomes for subacromial decompression and acromioplasty are equivalent to or even slightly inferior to those of conservative treatments such as exercise (Ketola *et al.* 2009; Saltychev *et al.* 2015; Ketola *et al.* 2017; Saltychev *et al.* 2020). In a randomised control trial (RCT) with five year follow up, patients that did not do well with non-operative treatment (exercise therapy), and subsequently had surgery, did not improve significantly (Ketola *et al.* 2015). Given the higher costs and risk of complications associated with surgery, some authors have recommended that RC should preferably be treated non-operatively (Diercks *et al.* (2014), Saltychev *et al.* 2020) with Ketola *et al.* (2017) concluding that subacromial arthroscopic decompression is not recommended in the management of RC tendinopathy. A large, randomised, multi-centre, placebo-controlled group trial compared ASD with investigational arthroscopy and no treatment and found that while the surgical groups

had a small clinically insignificant superior outcome for shoulder pain and function than no treatment, ASD had no extra benefit over arthroscopy only with the authors attributing the benefits with surgery to placebo effect or post-operative physiotherapy (Beard *et al.* 2018).

There has been debate in the literature regarding the effectiveness of surgery for RC tears. Some systematic reviews have suggested that there may be more improvement in shoulder function with surgery compared with conservative treatment for small to medium tears (Huisstede *et al.* 2011). However, recurrent cuff tears post-surgery are common (20-90%) and a meta-analysis by Russell *et al.* (2014) suggested that there is no strong correlation between shoulder function and rotator cuff structural integrity after surgery questioning the rationality/legitimacy/validity of surgical repair. A systematic review and meta-analysis (Ryösä *et al.* 2017) comparing the evidence for effectiveness of tendon repair in reducing pain and improving function of the shoulder with conservative treatment of rotator cuff tears found that although there are small differences in favour of surgery, the differences were clinically insignificant at one year follow up. The authors concluded that surgery is not more effective in treating symptomatic rotator cuff tears than conservative treatment and recommended a conservative treatment approach initially. Only limited conclusions can be drawn from this study as analysis of the results was limited due to the small number of pooled participants and the mixture in terms of mechanism of injury/history (acute and degenerative tears were included in one RCT) further trials comparable trials are recommended investigating traumatic and non-traumatic separately.

The number of patients undergoing subacromial decompression in England rose by seven times from 2000 to 2010 and rotator cuff repair used in conjunction with

subacromial decompression increased tenfold from 2004/2005 to 2009/2010 (Judge *et al.* 2014). However, a recent study on shoulder surgery rates in Scotland (Jenkins *et al.* 2020) showed that there has been a clear decrease in the number of ASDs (29%) performed between 2014 and 2018 and number of rotator cuff repairs decreased by 15% in the same time period. The authors speculated that this may be due to better awareness of the results of RCTs, such as the CSAW trial mentioned above, familiarity with epidemiological studies and up-to-date referral guidelines.

### ***1.7.2 Conservative treatment***

There is growing evidence for effectiveness of exercise in managing rotator cuff tendinopathy (Kuhn 2009; Hanratty *et al.* 2012; Abdulla *et al.* 2015), particularly loaded exercise (Littlewood *et al.* 2012; Naunton *et al.* 2020). An umbrella review of conservative physical therapy interventions for subacromial pain (Pieters *et al.* 2020) gave a strong recommendation for exercise therapy. Expert consensus (Klintberg *et al.* 2015) recommends a limited number of graduated exercises, which are non-provoking, performed well, individually prescribed and progressed from simple to complex movements in addition to addressing all contributing factors. Despite the strong recommendations and guidelines supporting the use of progressive resisted exercise as a first line treatment for the management of rotator cuff tendinopathy, a study by Ylinen *et al.* (2013) found that 49% of patients undergoing surgery for subacromial pain had never been instructed in resistive exercise. Whether this is due poor adherence to exercise on patients' part or a failure of the consulting physician to recommend physiotherapy prior to referring for an orthopaedic consultation is unclear (Ylinen *et al.* 2013). A study by Dupuis *et al.* (2018) comparing cryotherapy with gradual reloading for acute RC tendinopathy produced similar outcomes when loading was

introduced carefully, and authors speculated that exercise may provide a better remodelling stimulus than rest and cryotherapy.

The Pieters *et al.* (2020) umbrella review also gave a strong recommendation for the inclusion of manual therapy with exercise for subacromial pain in the short term. However, heterogeneity in the content of the manual therapy interventions studied makes it unclear what type of manual therapy is beneficial. Yiasemides *et al.* (2011) found no evidence for the use of passive mobilisations of the shoulder region joints in addition to exercise in patients with shoulder pain without restriction of movement. Kromer *et al.* (2013) found no difference in outcome at 5 and 12 weeks between groups treated with exercise plus manual therapy compared with exercise alone. At one year follow up, the exercise only group continued to improve following treatment but the combined manual therapy with exercise group did not (Kromer *et al.* 2014). The authors suggested that the exercise only group more strongly associated improvement with exercise and had a stronger belief in its effectiveness.

Interventions directed at relieving pain can give symptomatic relief in the short-term but do little to alter the underlying cause of symptoms. Studies comparing exercise with corticosteroid injection have shown a greater improvement in pain and disability in the short term for subjects treated with steroid injection combined with exercise and manual therapy compared with exercise and manual therapy only. The medium- and long-term results showed no difference between groups (Crawshaw *et al.* 2010). There is lack of evidence for the effectiveness of electrotherapy in managing subacromial pain with Pieters *et al.* (2020) recommending against its use. The effectiveness of multimodal therapy is unclear possibly due to the heterogeneity/mixture/array of modalities used. (Pieters *et al.* 2020).



In summary, surgical outcomes are equivalent to conservative treatments. In terms of physiotherapy interventions, exercise has better long-term outcomes than injection therapy, manual therapy in conjunction with exercise is appropriate in acute pain states and electrotherapy is not recommended. Exercise is also appropriate in acute presentations when introduced carefully and may provide a better remodelling stimulus than rest. The efficacy of multi-modal therapies is unclear.

### ***1.7.3 Mechanism of action of exercise***

#### **1.7.3.1 Physiology of loading**

Some treatments aim to improve the load bearing capacity of tendons. Studies undertaken to investigate the response of tendon to loading have demonstrated that tensile loading via progressive resisted exercise can stimulate reconditioning and result in improved ability of the tendon to cope with load (Kjaer and Heinemeier 2014; Mersmann *et al.* 2017). Mechanotherapy (Khan and Scott 2009) is the term used for the process by which therapeutic loading of structures (tendons) stimulates tissue healing, repair and remodelling.

#### **1.7.3.2 Psychological and health benefits of exercise**

The benefits of exercise are not limited to the effects on tendon mechanical properties. Exercise is known to be associated with reduced risk of all-cause mortality including cardiovascular disease, stroke, and diabetes (Lee *et al.* 2012). A cross-sectional study of over 1.2 million adults found that all forms of physical exercise were associated with a lower mental health burden (Chekroud *et al.* 2018). A systematic review by Hanratty *et al.* (2012) found that exercise has a small, statistically insignificant impact

on mental health function in RC tendinopathy patients and concluded that there is moderate evidence that exercise results in short-term improvement in wellbeing.

#### ***1.7.4 Considerations in exercise prescription***

##### **1.7.4.1 Parameters**

High loads, 80% of 1 Repetition Maximum (RM) produce optimal improvements in tendon stiffness and elasticity (Malliaras *et al.* 2013), however this study used young healthy volunteers, so the findings may not be applicable to a clinical population. There is convincing evidence that fatiguing exercise, particularly with high frequency loading cycles, has a deleterious effect on the tendon (Neviaser *et al.* 2012). McCreesh *et al.* (2017) found that normal asymptomatic tendons returned to their pre-exercise width within 6 hours of fatiguing exercise whereas symptomatic degenerative tendons took far longer to recover. Mersmeann (2017) suggests that the length of time that the tendon is loaded may be the critical factor and recommended low a frequency of repetitions with rest periods repetitions. The positive results from an RCT using heavy slow resistance (Kongsgaard *et al.* 2009) concur with this. However, this protocol devised for patellar tendinopathy.

Although there has been a trend amongst researchers to favour eccentric exercise programmes (Jonsson *et al.* 2006; Bernhardsson *et al.* 2011), the mechanisms behind the efficacy of eccentric exercise remain unknown (Camargo *et al.* 2014). It may be that eccentric exercise generates more mechanical stress in the tendon and promotes a better remodelling stimulus (Camargo *et al.* 2014; Kjaer and Heinemeier 2014). Good clinical results with eccentric training for painful Achilles tendinopathy are associated with a decrease in vasculo-neural ingrowth which is thought to be a likely source of pain Chansky and Iannotti (1991)(cited in Jonsson *et al.* 2006).

A systematic review by Littlewood *et al.* (2015) explored prescription parameters of exercise programmes for rotator cuff tendinopathy and learned that high-dose protocols seemed to have an advantage over low dose and exercise programmes should be carried out for a minimum of 12 weeks. Smith *et al.* (2017) investigated the effectiveness of exercise programmes that advocated exercise into pain versus pain free exercise for chronic musculoskeletal conditions. This review included four studies on shoulder pain and found that while the overall long-term result was the same, the patients exercising into pain had a better result in the short term and pain during exercise need not be avoided.

The American College of Sports Medicine guidelines for resistance training recommend starting with 1 set of 8-12 repetitions for healthy subjects and 10-15 repetitions for frail/older patients (Ratamess *et al.* 2009). Most programmes mentioned in the literature used 15 repetitions and either two or three sets daily. This is in contrast to the low repetitions recommended by Neviasser *et al.* (2012). to avoid adverse effects on tendons.

#### **1.7.4.2 Protocols**

Exercise protocols developed by Jonsson *et al.* (2006) and Bernhardsson *et al.* (2011) used painful eccentric strengthening of the posterior/superior cuff using an endurance type of training programme in patients with chronic subacromial pain. Both advocated twice daily training for a period of 12 weeks. Both training programmes resulted in good outcomes with more than half of the waiting list patients in Jonsson's study opting not to have surgery.

In response to the need to offer fewer physiotherapy appointments in the NHS and in recognition of the fact that patients are less likely to comply with home exercise

programmes when multiple exercises are prescribed, (Littlewood *et al.* 2016) adapted the exercise programme devised by Jonsson *et al.* (2006) which involved high loading of rotator cuff in one movement plane/direction (the most symptomatic one) using one exercise, reasoning that as the tendons of the cuff are conjoined, when one muscle is activated, the whole cuff is loaded. This was investigated in an RCT and equivalent results were obtained with this protocol when compared with usual physiotherapy care. This study, however, was underpowered and so it may have failed to detect any difference between groups that may have existed. It was also subject to detection bias as the treating therapists assessed outcomes.

Holmgren *et al.* (2012) investigated if specific exercises were more beneficial than non-specific (range of motion) exercises in patients with chronic RC tendinopathy who had previously failed conservative treatment and were listed for surgery. Yet again, the requirement to limit the number of exercises given in the home exercise programme (HEP) was recognised and was accordingly limited to between four and six exercises. There was some progression in terms of the numbers of exercises included and the resistance used but the number of repetitions remained the same. Exercises included were eccentric only, concentric-eccentric and one stretch was included in the protocol. The results were strongly in favour of the specific exercise programme with a much higher proportion opting not to undergo surgery in the specific exercise group compared with the non-specific group. However, the study has been criticized for having a larger number of full thickness tears in the control group compared with the experimental group as this may have influenced outcome (Lewis 2012). A five year follow up reported that improvements with specific exercise were maintained (Björnsson Hallgren *et al.* 2017).

Ingwersen *et al.* (2017) compared high-load exercise with low-load exercise programmes and found no difference in Disability of the Arm, Shoulder and Hand (DASH) scores between the two groups. Nevertheless, a significant improvement in tendon neovascularity was observed in the high load group only which points to an improvement in structure. There was also an interesting finding that patients who were injected with cortisone did better with high load exercise than low load. Decreased pain inhibition may be a factor, but as the study was underpowered it is difficult to draw any firm conclusions and that may be the reason why a significant between group difference was not observed.

In addition to exercises that are specifically directed at loading the rotator cuff and improving scapular control, there is a role for lower limb/whole body exercise. Kibler (1995) noted that 40% of the force required for performing upper limb tasks such as serving at tennis or javelin throwing is generated by the lower limbs and transmitted via the trunk to the upper limbs. It is obvious then that whole-body conditioning should be included as part of the rehabilitation programme for the shoulder, particularly when the onset is related to overuse of the upper limb. Richardson *et al.* (2020) recommended kinetic chain exercise to reduce demands on rotator cuff muscles, noting that non-kinetic chain exercises may be preferable when the rehabilitation goal is to isolate and strengthen the rotator cuff.

While the evidence in support of exercise is mounting, particularly progressive resisted exercise which is carried out over longer periods, the optimum dose, frequency, acceptable pain levels, mode of delivery (supervised or unsupervised) and duration of exercise programmes is still unknown.

### 1.7.5 Adherence

Adherence may be defined as “*the extent to which a person’s behaviour corresponds with agreed recommendations from a healthcare provider*” p17 (Sabaté and Sabaté 2003). Outcome is inherently associated with exercise adherence (Pisters *et al.* 2010; Sandford *et al.* 2017). Sluijs *et al.* (1993) suggested that non-adherence to home exercise could be as high as 70%.

Due to the slow nature of tendon remodelling, long-term exercise adherence is important as it will be necessary for patients to follow their exercise programmes for lengthy periods of time. A thorough appreciation of the role of strengthening exercise in management of tendinopathy is necessary for good exercise adherence as perceived benefit from exercises is an enabler to exercise adherence (Sandford *et al.* 2017). Other factors associated with exercise adherence are positive feedback from the physiotherapist, a good patient-therapist relationship and exercise self-efficacy ( the patients’ belief in their ability to do the exercises correctly) (Sluijs *et al.* 1993; Chen *et al.* 1999; Jack *et al.* 2010; Sandford *et al.* 2017).

Adherence to exercise is linked with severity of symptoms as they act as a motivator to exercise (Sluijs *et al.* 1993; Sandford *et al.* 2017) with Sandford noting that patients are not motivated to exercise to prevent the condition. Conversely, pain, especially pain that worsens with exercise, has been identified as a barrier to adherence with treatment and exercise (Jack *et al.* 2010; Sandford *et al.* 2017). Littlewood *et al.* (2013a) considered the presence of central sensitisation in RC tendinopathy and reasoned that reframing the experience of pain as not harmful, while participating in exercise programmes, has the effect of reducing fear and encouraging pain self-efficacy (a belief in the ability to carry out a task despite pain).

### **1.7.6 Role of psychological factors in management**

Anxiety, depression, self-efficacy and social factors can all have an influence on adherence and hence recovery (Jack *et al.* 2010).

Chester *et al.* (2018) found that psychosocial factors are associated with outcome of physiotherapy in patients with shoulder pain. Patients' expectation of recovery with physiotherapy at baseline was the best predictor of outcome, with higher expectations of recovery predicting a better outcome in terms of patient reported pain and disability. Similarly, a study by Dunn *et al.* (2016) on patients with full thickness RC tears revealed that a patient's expectation regarding the effectiveness of physiotherapy was a stronger predictor of progression to surgery than severity of tear or symptoms. Higher pain self-efficacy is also a major predictor of a favourable outcome in patients receiving physiotherapy for shoulder pain (Chester *et al.* 2018; De Baets *et al.* 2019).

Psychological factors such as positive personality traits can have a mediating effect in the experience of pain with MSK conditions (Wong *et al.* 2020) and De Baets *et al.* (2019) found a moderating role for optimism in the relationship between pain catastrophising and disability associated with shoulder conditions.

Other factors such as the patient-therapist relationship can influence outcome for patients with musculoskeletal (MSK) conditions, with positive patient-therapist interactions associated with improved function and increased treatment satisfaction (Hall *et al.* 2010; Barrett *et al.* 2018).

The prevalence of psychosocial factors which are associated with higher levels of pain and disability in patients with RC tendinopathy (Wong *et al.* 2020) and the potential for negative psychosocial factors to influence central pain processing mechanisms

(Plinsinga *et al.* 2015) highlight the need to consider the use of biopsychosocial interventions such as cognitive-behavioural strategies and education of patients with rotator cuff tendinopathy on the effects of psychological factors in the management of the condition (Maxwell *et al.* 2020; Wong *et al.* 2020)

### ***1.7.7 Role of Education***

Recent qualitative research has revealed that patients have a biomedical interpretation of shoulder pain (Gillespie *et al.* 2017; Page *et al.* 2019; Maxwell *et al.* 2020). Patients expect and are satisfied with diagnoses and explanations that provide a structural explanation for their pain. However, this may create a barrier to engagement with effective rehabilitation if they believe that their symptoms are the result of structural defects that cannot be corrected with physiotherapy or that exercise may cause further harm (Cuff and Littlewood 2018).

Advice and education as part of a biopsychosocial approach empowers patients to manage their condition. When patients understand their condition, it enables them to participate in shared decision-making and to take more responsibility for their condition (Traeger *et al.* 2017; Bernhardsson 2018). Failure to provide practical advice and education can lead to increased levels of anxiety, reduced self-efficacy, reduced compliance with rehabilitation and increased dependence on their therapist (Meehan *et al.* 2020). There is a need for education about the multifactorial nature of RC tendinopathy, the role of lifestyle factors and pain mechanisms in persistent pain states (Lewis 2016; Gillespie *et al.* 2017). Patients also benefit from advice on modification of activities and education on the effectiveness of progressive resisted exercise and realistic timescales for recovery (Lewis 2016; Sandford *et al.* 2017)



A scoping review by Meehan *et al.* (2020) of current practice with regard to education and advice given by physiotherapists to shoulder pain patients. While 88% of treatment sessions included advice and education, the most common advice given is regarding exercise intensity, pain response to exercise, activity modification advice and postural advice. Behavioural approaches such as goal setting, motivation, positive reinforcement, reassurance and mental imagery while performing exercise was utilised/reported in only 7% of studies. However, the author acknowledged that these strategies are commonly employed in practice and difficult to separate out from other elements of treatment. Few (2%) included education on pain biology suggesting a lack of confidence in delivering this type of education. This concurs with the findings of a qualitative study exploring clinicians views on education for shoulder pain patients (White *et al.* 2020). This study reports that while therapists believe that education is important to clear up beliefs which may be a barrier to exercise, to engage patients in the rehabilitation process and to build a therapeutic relationship alliance, they lack confidence in delivering education.

Education needs to extend beyond a local tissue pathology model to include neurosciences and provide advice which is patient-centred and considers the patient's level of health literacy, goals and concerns (Maxwell 2020; Meehan 2020).

## **1.8 Group vs Individual treatment**

### ***1.8.1 Equivalent outcomes with group versus one-to-one***

In a systematic review, O'Keeffe *et al.* (2017) found that group-based and individually delivered exercise treatment programmes were equally effective in treating pain and disability for musculoskeletal conditions. One of the studies included in the review (Russell *et al.* 2014) was a randomised trial which compared individual treatment for

frozen shoulder to group exercise (and home exercises) and found superior outcomes for those attending the group. Ryans *et al.* (2020) found group exercise to be as effective as individual physiotherapy treatment for patients with RC tendinopathy. Abramson (2018) evaluated a class run for patients with RC tendinopathy and found positive outcomes for pain and disability and recommended that such patients should be routinely directed towards class-based treatment. However, this study was limited by the lack of a control group.

### ***1.8.2 Group treatment may be more cost effective***

Group based treatments may be more economical (Carr *et al.* 2005; Lewis *et al.* 2005; Ryans *et al.* 2020). A study by Carr *et al.* (2005) for chronic lower back pain found similar outcomes for patients treated in a group compared to individual treatment and cost savings not only in terms of therapist time but also in use of secondary care. Patients treated in a group who sought further treatment were inclined to seek more GP and physiotherapy treatment, whereas those who were treated individually went on to have surgery and other interventions such as injection therapies. Similarly, Ryans *et al.* (2020) found considerable cost savings in terms of therapist time for participants treated with group versus individual physiotherapy (Mean(SD) cost of treatment per patient: £74.53(33.64) Group, £188.59(96.01) Individual) in primary care.

### ***1.8.3 Positive experiences with groups***

Barrett *et al.* (2018) found that patients attending a class for shoulder pain valued the knowledge and expertise of the therapists and gained an improved understanding of the importance of exercise in managing their condition even though education was not formally included in the class. Previous research in low back pain (Lewis *et al.* 2005; Kaapa *et al.* 2006) observed that there are additional benefits to group-based therapies

with participants reporting positive experiences associated with peer support and social interaction. Barrett *et al.* (2018) revealed a preference for group-based treatments over individual treatment in those participants who had previously attended individual physiotherapy.

#### ***1.8.4 Supervision and self-efficacy***

A recently published systematic review (Gutiérrez-Espinoza *et al.* 2020) indicates that outcomes for patients with RC tendinopathy are equal with supervised and unsupervised exercise. Holmgren *et al.* (2012), however, detected significantly greater improvements in patients post arthroscopic subacromial decompression whose exercise programmes were supervised compared with those who exercised at home. Supervision and contact with the therapist are likely to improve exercise self-efficacy. Thorstensson *et al.* (2006) reported supervision to be a key factor in performance of a HEP amongst osteoarthritis knee pain patients because patients forget or misunderstand about 12% of therapists' home exercise programme recommendations (Chen *et al.* 1999).

As mentioned previously self-efficacy is strongly associated with exercise adherence and persistence when faced with setbacks. According to the Bandura cognitive theory of self-efficacy, there are four sources of self-efficacy - mastery experience, vicarious experience, verbal persuasion and physiological feedback (Jones 2006). All of these elements are present in a class. Supervision is a form of verbal persuasion where a significant other (healthcare professional) provides constructive feedback and validates competence in carrying out exercises. Patients attending an exercise class have the opportunity to practise their exercise with supervision whereas individual

physiotherapy sessions only allow time for reviewing and modification of exercise programmes.

To date, studies comparing group exercise classes to one to one treatment for MSK conditions have compared equal numbers of treatment sessions with numbers of classes attended. No study has compared individual treatment to a group/class which is run frequently enough to give patients the opportunity to complete all of their exercises under supervision (e.g. twice a week for six weeks).

#### ***1.8.5 Positives of one-to-one treatment***

Increasingly, research into RC tendinopathy is demonstrating that causes are multifactorial and that the effective treatments need to be multidimensional (Klintberg *et al.* 2015). As mentioned above, in a recent systematic review on conservative interventions for subacromial pain Pieters *et al.* (2020) gave a strong recommendation for the use of manual therapy in addition to exercise. One-to-one physiotherapy allows therapists to recognise and address the individual contributing factors and permits therapists to choose from a variety of modalities whereas group interventions have been criticised for having a one size fits all approach (Sandford *et al.* 2017). Previous research has highlighted that patients value the patient-therapist interaction and that the patient-therapist relationship can have a powerful influence on outcomes (Hall *et al.* 2010; O'Keeffe *et al.* 2016). There is a risk of losing that relationship effect in a class.

### **1.9 Rationale for study**

There is growing evidence for the effectiveness of exercise as a treatment for rotator cuff tendinopathy (Kuhn 2009; Hanratty *et al.* 2012; Abdulla *et al.* 2015; Pieters *et al.*

2020). What is not clear is whether this type of intervention is best delivered in a group/class format or whether one-to-one, multi-modal physiotherapy intervention leads to superior outcomes. Group exercise may potentially be a more resource-efficient way of delivering treatment to this patient group. A systematic review and meta-analysis of group and physiotherapy interventions for musculoskeletal disorders by (O'Keeffe et al. 2017) has shown similar outcomes in terms of pain and disability for musculoskeletal conditions for both one-to-one treatment and group exercise. To date, there has been only one published study comparing one to one treatment with group exercise in primary care for the treatment of rotator cuff tendinopathy (Ryans *et al.* 2020). This study compared six sessions of group exercise with six individual treatment sessions in patients with subacromial impingement syndrome who received a subacromial corticosteroid injection. However, not all patients presenting to physiotherapy in primary care will have access to a corticosteroid injection. While the Ryans *et al.* (2020) study was not prescriptive in terms of content of treatment, therapists (in partnership with patients) should be free to decide on the number of treatment sessions provided.

There is a need for a study to compare a group intervention with an individual treatment intervention which is more reflective of usual primary care practice. There is also a need to evaluate the effectiveness of a group intervention which offers a progressive resistance programme which is tailored to the individual where exercises are supervised, and sessions are of adequate frequency.

## **1.10 Thesis Layout**

This thesis comprises two studies:

1. a randomised control trial (RCT) comparing group and individual physiotherapy for the management of rotator cuff tendinopathy in primary care.
2. a qualitative study examining participants' experience of and preference for both formats of treatment delivery.

The RCT study is presented as a set of chapters (Methods, Results, Discussion and Conclusion) which allows for a more detailed description of the work undertaken, whereas the qualitative study is presented as a single chapter in its entirety, in publication format, illustrating the ability to format a study for publication.

## **CHAPTER 2      Methods**

### **2.1 Aim**

The primary aim of this trial was to investigate whether group exercise is as effective as multi-modal individual physiotherapy in the management of rotator cuff tendinopathy in a primary care setting. This chapter describes the methodology of the randomised control trial which compared the two treatments.

### **2.2 Study Design:**

An assessor-blinded randomised two-group trial was undertaken to compare the effectiveness of group versus individual physiotherapy for rotator cuff tendinopathy using the Shoulder Pain and Disability Index (SPADI) to assess changes in pain and disability from baseline to 6 weeks, 3 months and at 6 months. The conduct and reporting of this study adhered to the CONSORT standardised reporting guidelines (Schulz *et al.* 2010) (Appendix A). In addition, a qualitative study using semi-structured interviews was undertaken to explore patients' experiences of and preferences for the two formats of treatment delivery. The methodology for the qualitative component of the study is described in Chapter 5.

### **2.3 Hypothesis**

The null hypothesis is that there is no difference between group exercise and multimodal one-to-one physiotherapy, in the management of rotator cuff tendinopathy, as measured by pain and disability domains of the SPADI self-rated outcome measure.

## 2.4 Participants:

*Table 1* lists the eligibility criteria for the study.

**Table 1** *Inclusion and Exclusion Criteria*

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> <li>aged over 18</li> </ul>	<ul style="list-style-type: none"> <li>aged under 18</li> </ul>
<ul style="list-style-type: none"> <li>a history of lateral arm pain – either traumatic or insidious</li> </ul>	<ul style="list-style-type: none"> <li>a history of upper limb fracture in previous 6 months</li> </ul>
<ul style="list-style-type: none"> <li>pain and/or weakness on resisted tests of the rotator cuff</li> <li>and/or positive on 3 of 5 pain provocation tests (painful arc in Flexion or ABDuction, pain on resisted lateral rotation, positive empty can, Hawkins-Kennedy or Neer’s test* (Michener <i>et al.</i> 2009).</li> </ul>	<ul style="list-style-type: none"> <li>a history of shoulder surgery in previous 6 months</li> </ul>
	<ul style="list-style-type: none"> <li>a diagnosis of frozen shoulder</li> </ul>
	<ul style="list-style-type: none"> <li>a history of shoulder instability</li> </ul>
	<ul style="list-style-type: none"> <li>a massive irreparable cuff tear</li> </ul>
	<ul style="list-style-type: none"> <li>repeated spinal movements reproducing the shoulder symptoms</li> </ul>
	<ul style="list-style-type: none"> <li>radicular neck pain with paraesthesia or hard neurological signs related to their neck pain.</li> </ul>

\* See Chapter 1

Exclusion criteria were determined by patient self-report and on objective assessment during the screening assessment:

## 2.5 Recruitment

All eligible participants were referred to physiotherapy by their general practitioner (GP). Potential participants were recruited from the existing waiting list of the department. In addition, a recruitment letter (Appendix B) informing GPs about the study and requesting them to refer suitable patients was sent to all GPs in the catchment area served by Blackrock Hall physiotherapy department.



Participants were screened by one of the three senior physiotherapists<sup>1</sup> (who all had greater than 10 years' experience, these physiotherapists also delivered the group exercise intervention) involved in conducting the study using a shoulder assessment form (Appendix C). The screening involved taking a detailed history of onset, aggravating and easing factors, lifestyle factors, medical, drug and social history. Objective examination consisted of assessment of joint range, observation of active shoulder movement to ascertain muscle recruitment patterns and motor control, palpation and a thorough spinal examination where there was a suspicion of pain from spinal origin.

Patients who were not eligible for the study or who did not consent to participate in the study were offered treatment by the physiotherapist who screened them.

Other demographics and confounding variables such as age, gender, whether dominant hand was affected, onset (traumatic/insidious), presence of diabetes, findings on imaging, previous treatment or treatment with steroid injection determined during the screening assessment were also recorded. These variables may have an influence on the response to treatment and it is useful to see if these variables were evenly distributed between the two groups. As recommended by the CONSORT statement (Schulz *et al.* 2010) they were presented in a table in Chapter 3.

### ***2.5.1 Settings and locations where data collected***

The study took place in Blackrock Hall primary care physiotherapy department. This physiotherapy department serves both an urban and rural population and receives referrals for neurorehabilitation, care of the elderly and musculoskeletal patients. The centre receives referrals from approximately 20 GP practices. All patients are medical card holders. It is

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<sup>1</sup> KT, SL and DK

staffed by three neurorehabilitation and five musculoskeletal physiotherapists (all part-time). All referrals for musculoskeletal physiotherapy are received from primary care GPs and most referrals received are chronic in nature. The department is comprised of separate treatment cubicles and a large gym (where the group exercise class was conducted).

## **2.6 Interventions:**

The individual treatment group received standard one-to-one physiotherapy at their treating therapist's discretion in terms of treatment received and number of sessions. The other arm of the study received their treatment in a group exercise class which consisted of one hour of circuit-based exercises and education twice weekly for six weeks. All participants were advised to inform their therapist(s) if they had a steroid injection or commenced on oral steroids while participating in the study.

### ***2.6.1 Group-Based Exercise:***

#### **Format of class:**

The group intervention consisted of 12 sessions (twice a week for six weeks) of a circuit-type exercise class which was one hour in duration (**Figure 4**). This number of sessions and time period was chosen to ensure that participants had adequate time to master their exercise technique, gain an understanding of load management and exercise progression as well as how to monitor their symptoms. The time period over which the classes ran was chosen to approximate a time-frame similar to a standard block of treatment. A systematic review by Littlewood *et al.* (2015) recommends that exercise programmes should be continued for 12 weeks. However, six weeks is a reasonable time-period for a class to run for pragmatic departmental reasons i.e. availability of gym and therapist time. It is also enough time for patients to notice a change in their symptoms and therefore be convinced

of the benefits of adopting the exercise routine. The intention was that once patients had mastered their exercises and were persuaded that they were beneficial for managing their symptoms/condition that patients would be instructed to continue with their exercise programme 2-3 times weekly for at least 3 months. As the optimal frequency for exercising with rotator cuff tendinopathy is unknown (see Chapter1), the frequency chosen was in line with recommendations from the American College of Sports Medicine guidelines for resistance training (Ratamess *et al.* 2009) which advocates training a minimum of twice a week on non-consecutive days and twice a week was a reasonable expectation for patient attendance and for the physiotherapy department to accommodate.

In the first session, participants were introduced to the circuit of exercises in pairs to familiarise them with the exercises, during this session the exercise was demonstrated by the physiotherapist then each participant had the opportunity to practise the exercise with 1:2 supervision (**Figure 4**). All subsequent classes followed the same format - the participants performed warm up exercises in a group consisting of cervical spine, thoracic spine and shoulder girdle range of movement (ROM) exercises followed by pendular exercises. Education on posture was also given at this point in the class – in standing, class participants were instructed on achieving neutral spine posture (lumbar, thoracic and cervical) and optimal shoulder girdle positioning. They then exercised independently(individually) to allow for tailoring of the exercise programme, individual/personal interaction with the therapists so that they could bring up specific questions or concerns and to allow participants to work at their own pace (**Figure 3**). The circuit consisted of 10 exercises to be completed in random order and details of repetitions and resistance bands/weights used were recorded on an exercise log (Appendix D). This approach to recording of exercise was used to promote independence amongst participants

in performing the set exercises and to give them an appreciation of how they were progressing throughout the sessions (*Figure 3*).

Role of physiotherapists 2 per class	Role of participants 8 per class
<ul style="list-style-type: none"> <li>• to supervise and modify exercises</li> <li>• ensure good technique</li> <li>• to guide exercise progression with reps/weights</li> <li>• provide education piecemeal in line with patient information leaflet</li> <li>• Answer any patient questions and ensure adequate interaction with all participants</li> </ul>	<ul style="list-style-type: none"> <li>• to record exercises on exercise log</li> <li>• to report any increase in symptoms</li> <li>• to seek help as required</li> </ul>

**Figure 3** *Roles of therapists and class participants*

### **Type of exercise**

There is some evidence to suggest that loaded exercise is of most benefit in this population (Chapter 1). All the exercises in the circuit were progressive and included strengthening exercises for the rotator cuff, to promote tendon remodelling and centring of the head of the humerus in the glenoid fossa, and the scapular stabilisers to make scapula a stable base for the rotator cuff muscles to function on. Lower limb exercises were included as the force required to carry out many activities using the shoulder requires an intact kinetic chain (see Chapter 1). Some of the exercises included in the circuit (Appendix E) were eccentric (progressing to concentric/eccentric) as per the Holmgren protocol ( Holmgren *et al.* 2012).

## **Parameters**

There is a lack of detail in the literature about optimal parameters for strengthening programmes of the shoulder (see Chapter 1). Holmgren *et al.* (2012) used 3 sets of 15 repetitions in an RCT comparing a specific exercise programme with nonspecific exercises for patients with chronic subacromial impingement syndrome. So, these parameters were used as a rough guide. Patients were encouraged to work to fatigue with good form.

## **Supervision**

The sessions were supervised by two senior physiotherapists (**Figure 3**). The goal of the class was that it would be progressive and structured. The therapists also gave guidance on numbers of repetitions to be performed and weights/resistance bands used to ensure correct load management i.e. to progressively load tendons to stimulate collagen synthesis.

## **Exercise progression**

Progressive resistance training (Lombardi *et al.* 2008) was used to gradually load the tendons. The rule of thumb was that a maximum of 15 repetitions of any exercise was permitted and once the participant could perform that comfortably they were advised to increase the resistance (weight/band) and reduce the repetitions to 8-10 repetitions depending on comfort/fatigue. In subsequent sessions they were instructed on how to increase the numbers of repetitions. They were allowed to have a small amount of pain (i.e. NRS of 1 or 2 but were advised to stop if NRS increased to 4 or 5) as per the pain monitoring model (Thomee 1997). They were also advised to monitor their symptoms over the 24-hour period following the class and were encouraged to report back if there was an increase in night pain or an increase in their usual pain the day following the class (**Figure 3**). The exercise load was adjusted accordingly if an increase in symptoms was reported. Once they

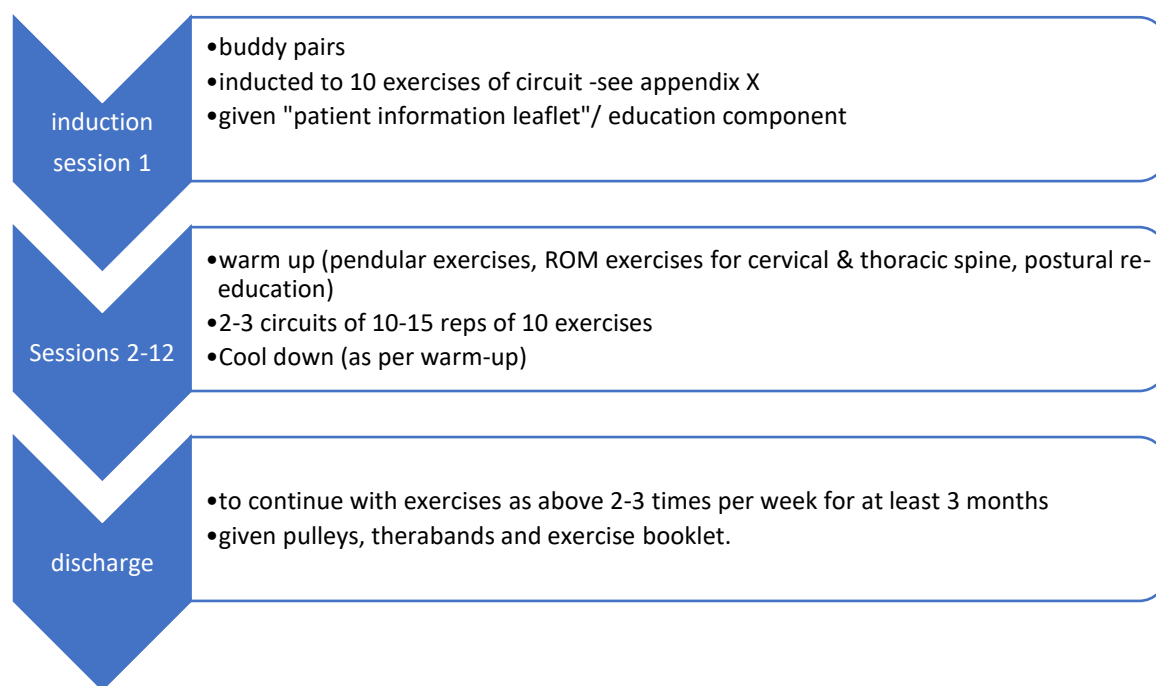
were familiar with the exercises, they were encouraged to complete two or even three circuits, as time allowed. Exercises described in the warm-up were performed again at the end of the class as a group (*Figure 4*).

### **Role of participants**

Participants were not expected to do their exercises at home while they were attending the class. This was to ensure that all performance of the exercise was correct as it was under the supervision of the physiotherapists delivering the intervention. It was also theorised that it might help with adherence to the programme after the class finished as participants would see that if they could set aside two or three hours in the weeks as they had done when attending the class, they would see the benefits. They were given an information leaflet (Appendix F) designed to educate them on rotator cuff tendinopathy (imaging, exercise, tips about healthy living and general exercise) as recommended by (Lewis 2016). The information contained in the leaflet was also given piecemeal by the supervising physiotherapists throughout the course of the six weeks.

### **On-going management**

At their last class, participants were given a booklet with pictures of the shoulder exercises and written instructions (Appendix G). These were also displayed on the walls during the classes. In addition, a set of pulleys and resistance bands was supplied to enable participants to continue their exercises at home for at least 3 months (*Figure 4*). They were encouraged to do them 2 or 3 times weekly, leaving a rest day between exercise sessions to allow for recovery from the effects of fatiguing exercise on tendon volume and subacromial space



**Figure 4** *Format of class*

### **2.6.2 Multi-modal individual treatment:**

The usual care group received their physiotherapy at individual appointments, these sessions ran in parallel with the group exercise class. Treatment was delivered by therapists with experience of working in primary care, a senior physiotherapist<sup>2</sup> and a basic grade physiotherapist<sup>3</sup> both with over 10 years' experience. The physiotherapists were not restricted as to the treatment modalities (e.g. manual therapy, exercise, dry needling, advice) they used, as this was to reflect standard practice or usual care. There was no limit to the number of treatment sessions or the time between sessions in the usual care group. This was provided at the treating therapists discretion and as normal timetabling allowed. **Table 2** below shows the different modalities used in the treatment of the individual treatment arm of the study. The frequency refers to the number of times that modality was

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<sup>2</sup> AC

<sup>3</sup> LA

prescribed amongst participants and as one would expect most if not all participants received a combination of multiple modalities. Participants typically received between one and five sessions; initial appointments were for one hour with follow-up sessions lasting 30 minutes.

Exercise-based treatments are advocated in this patient group and the effectiveness of exercise as a treatment modality has been proven. In general, a self-management approach was used with exercise and advice forming the mainstay of treatment used. This approach has been advocated for chronic MSK conditions (May 2003). However, all treatment modalities were available to the treating therapists and, although some were used less frequently, all were used.

All participants in the individual treatment group were given a HEP with strengthening being the most often prescribed followed by stretching and range of movement. Frequency, when documented, was either once or twice daily, intensity generally ten repetitions for ROM/strengthening and five repetitions for stretches. Progression of the HEP was not usually documented but in some cases more resistive band was supplied. Advice to continue with HEP was only documented twice, however, information from the interviews suggest that participants were advised to continue with their HEP, but the duration advised is not known. As the frequency and timing of appointments was at the treating physio therapist's discretion, not all participants had completed their treatment by the six-week follow-up.



**Table 2** Treatment modalities used in Individual treatment sessions

<b>Treatment modality</b>	<b>Brief explanation &amp; frequency modality was used/prescribed*</b>
<b>ROM exercises – shoulder</b>	GHJ – 15, Shoulder girdle - 8
<b>ROM exercises – Spinal</b>	Cervical – 5, Thoracic - 5
<b>Stretching</b>	Sleeper stretch – 11, Scalenes/UFT – 8, Pectorals (minor, major)-8, Latisimus dorsi/Thoracic Extension - 2
<b>Strengthening exercise</b>	Rotator Cuff – 22, scapular 25, biceps/triceps - 3
<b>Hydrotherapy</b>	Shoulder strengthening all directions
<b>Advice</b>	Heat – 15, Physical Activity levels – 8, healthy lifestyle – 1, neck pillow/pillow advice – 2, STM – 4, pacing -, ice-1.
<b>Education</b>	Aging/OA/Stiffness – 5, Anatomy/Inflammation/Posture-&Impingement – 2, Smoking – 2, Reassurance- 2, Long-term management shoulder condition – 1, Pain management – 1.
<b>Postural re-education</b>	Scapular setting – 2, upper quadrant - 1
<b>Electrotherapy</b>	Heat – 2
<b>Dry needling</b>	UFT/Infraspinatus/deltoid - 7
<b>Manual MTrP therapy</b>	UFT/Infraspinatus/Subscapularis/Triceps/Biceps/Deltoid/Paraspinals - 20
<b>Manual joint therapy</b>	GHJ – 1, cervical - 1

\*participants could receive multiple modalities

Legend: GHJ: glenohumeral joint, MTrP: myofascial trigger point, STM: soft tissue massage, UFT: upper fibres of trapezius.

## 2.7 Outcome measures (Appendix H)

In order for outcome measures to be of use for clinical and research purposes they must be valid, reliable and responsive (Gagnier *et al.* 2017). In this study, we used outcome measures whose psychometric properties have been previously studied. The Shoulder Pain and Disability Index (SPADI), Quick Disability of the Arm, Shoulder and Hand (QuickDASH) and Constant Murley Score (CMS) are the outcome measures that have been most frequently studied in rotator cuff disease (Huang *et al.* 2015). The Patient Global Impression of Change is a rating of change outcome measure which may be used as a reference standard against which responsiveness of other outcome measures are assessed. The OMERACT (Outcome Measures in Rheumatology) group worked on devising a core

set of domains to be used for assessing outcome in shoulder studies and recommended four mandatory domains which should be included. These are pain, physical function/activity, a patient rated measure of shoulder status and reporting of adverse events (which will be reported in results chapter as per the CONSORT statement (Schulz *et al.* 2010)). Four important optional domains identified were participation (work/recreation), sleep, emotional well-being and condition-specific pathophysiological manifestations (Ramiro *et al.* 2019). Our primary outcome measure, the SPADI, measures outcome in pain and physical function domains. However, in order to include most of domains suggested, the other outcome measures collected were the QuickDASH (pain, physical function, participation(work/social)), the CMS (pain, sleep, participation, physical function, range of motion and strength) and a global rating of change (GROC) measure – the PGIC.

Standardised outcome measures were administered by the outcomes’ assessor, who was blinded to the participants’ treatment allocation, at baseline and reassessed at 6-weeks, 12-weeks and 24-weeks. These time-points were chosen to capture change in the exercise group which was completed in 6-weeks. However, not all participants in the individual treatment group would have completed their treatment at this timepoint so further measures were taken at 12-weeks when all participants had completed treatment and again at 24-weeks to investigate if any changes observed at the 6 and 12-week time-points were maintained in the longer term.

<b>Reliability</b>
Reliability refers to the ability of an outcome measure to accurately distinguish between subjects. The Intra-class correlation co-efficient (ICC) can be used to measure the ability of an instrument to measure reliability (Ekeberg <i>et al.</i> 2008). An ICC of above 0.81 reflects excellent reliability (St-Pierre <i>et al.</i> 2016).
<b>Agreement</b>
Refers to the outcome measure’s ability produce the same result with repeated measures. The standard error of measurement (SEM) is used to measure agreement. An outcome measure with a lower SEM is better. The SEM is used to calculate the smallest detectable change (SDC). Ideally the SDC should

be smaller than the minimum clinically important difference (MCID) of the outcome measure (Thoomes-de Graaf <i>et al.</i> 2017).
<b>Validity</b>
Refers to an outcome measure's ability to measure what it is supposed to measure. Dimensions/aspects of validity include content validity, structural validity, criterion validity and construct validity or hypothesis testing. (Huang <i>et al.</i> 2015)
<b>Sensitivity to change/responsiveness</b>
Refers to an instruments capacity to accurately capture change (after an intervention) and correlates to a gold standard. Internal responsiveness is the ability of a measure to gauge change over time and is represented by the effect size (ES) and standardised response mean (SRM). ES and SRM are large if >0.8., moderate if 0.5-0.8 and small between 0.2-0.5 (St-Pierre <i>et al.</i> 2016). External responsiveness refers to the ability of the instrument to detect clinically meaningful change and is determined by comparing it with an external criterion such as the patient's global rating of change (GROC). (Chester <i>et al.</i> 2017)
<b>Minimal Clinically Important Difference</b>
The smallest change that is meaningful/relevant for the patient (St-Pierre <i>et al.</i> 2016). This is used to calculate the sample size.

### 2.7.1 SPADI (*primary*)

The SPADI is a shoulder specific patient rated outcome measure with pain and function domains. It is patient rated. It consists of 13 items (5 pain, 8 disability) each item is rated out of 10 on an NRS from 0 (no pain/difficulty) to 10 (worst pain imaginable/so difficult it requires help) with a higher score indicating higher pain and disability. The score cannot be calculated if more than one question in each domain has not been answered. The score may be separated into the 2 subscales for pain and function or combined. Scores are normally converted to a percentage. The minimum clinically important change is reported to be 15.4% (20 points) (Ekeberg *et al.* 2010). The SPADI has shown excellent reliability in patients with rotator cuff disorders. It demonstrates moderate to strong evidence for validity related to internal consistency, structural validity and construct validity and is highly responsive in improved subjects (Ekeberg *et al.* 2008; Huang *et al.* 2015; St-Pierre *et al.* 2016; James-Belin *et al.* 2019). (**Table 3**).

Rasch analysis of the structural validity of the SPADI found that the scale as a whole did not meet the standards needed in clinical trials for interval level of measurement (Jerosch-Herold *et al.* 2018). When divided into the pain and disability subscales, the pain subscale fits the model well, but the disability subscale required modifications to make it fit. The authors recommended separating the subscales and interpreting the results of the disability subscale with caution and referring to age and gender matched data. Consequently, results of the SPADI will be reported as both total scores and separate scores for pain and disability. The pre-specified study protocol does not mention reporting separate scores for the pain and disability subscales as the Jerosch-Herold *et al.* (2018) study referred to above had not been published when the protocol was submitted for ethics approval.

### **2.7.2 QuickDASH (secondary)**

The QuickDASH is a shortened version of the region-specific Disability of the arm, shoulder and hand (DASH) outcome measure. It consists of 11 questions with symptoms and physical function elements, whereas the DASH contains 30 items. There are two optional sections on sport/performing arts and work which were not assessed in this study. Each question is rated on a scale from none/no difficulty to maximum/unable. Each answer is equivalent to a score from 1-5 and the total score can be converted to a percentage with a higher score indicating higher disability. The score cannot be calculated if more than one question is unanswered.

Although not as widely tested as the DASH, it correlates well with the DASH (Franchignoni *et al.* 2014; Chester *et al.* 2017). The QuickDASH demonstrates excellent test-retest reliability, moderate correlations for validity and is highly responsive to change (Mintken *et al.* 2009; St-Pierre *et al.* 2016; Chester *et al.* 2017) (**Table 3**).

### **2.7.3 CMS (*secondary*)**

The CMS is a shoulder-specific, assessor and patient-rated outcome measure with a combination of subjective and objective components. Domains assessed are pain, function and impairment. Pain and function (activities of daily living (ADL), recreational activities) items are rated on a Likert scale. Objective elements assessed are abduction strength and active gleno-humeral range of movement (ROM), a combined score which ranges from 0 to 100 is calculated and may be compared with sex and age matched normative values, with a higher score indicating lower impairment and disability, “better functionality” (Constant *et al.* 2008). The CMS demonstrates good reliability and responsiveness, but the evidence for validity is inconsistent (Huang *et al.* 2015; Vrotsou *et al.* 2018; James-Belin *et al.* 2019) (**Table 3**).

Although the psychometric properties of the CMS are not as good as for the other outcome measures used, it is widely used in research and by other clinicians such as orthopaedic surgeons. The European shoulder and elbow society (EUSSER) has endorsed the CMS. For these reasons, the CMS was included.

### **2.7.4 Global Rating of Change (*Patient Global Impression of Change*)**

The patient global impression of change is a patient-rated outcome measure consisting of one question where patients are asked to rate the change in their condition from baseline/before treatment (“Please indicate the degree of change in your shoulder symptoms from the time you began physiotherapy treatment until now”). The rating is on a 7-point Likert scale from “worse than ever” to “very much better” with “no change” being the middle value. The measure is quick and simple to administer, easy for the patient to complete and for the clinician to interpret. It allows the patient to decide which elements of their condition they deem relevant. It may be used for a variety of conditions and is

frequently used to assess changes in musculoskeletal conditions. A major criticism of the global rating of change scales is that patients are unable to remember past health states accurately and the change score is disproportionately affected by the current status of the patient (Kamper *et al.* 2009). The scale is often used as a reference standard for the testing of other outcome measures but there has been little evaluation of the scales themselves (Bobos *et al.* 2020).

Several different GROC scales exist e.g., 7-point, 11-point, 15-point, which makes interpretation of the psychometric properties difficult. However, comparison of the 7-point with the 15-point scale found no significant difference in their responsiveness (Kamper 2009). A systematic review by Bobos *et al.* (2020) appraised the psychometric properties of GROC scales. Studies on low back pain, occupational MSK and upper extremity disorders were included. They found good to excellent test-retest reliability, moderate agreement and moderate to strong responsiveness. However, correlations for validity measures were moderate at best (**Table 3**). The authors have questioned the use of GROC scales as a reference standard in responsiveness studies. It should be noted that not all properties were tested for all conditions so some of the figures reported were for back pain or occupational disorders.

**Table 3** *Psychometric Properties of Outcome Measures*

Outcome measure	Domain	Scale	MCID	Reliability, Agreement	Validity	Responsiveness
<b>SPADI</b>	<b>Disability Pain</b>	<b>NRS</b>	15.4%/20 points (O. Ekeberg et al. 2010)	<b>ICC</b> between 0.85 (Ekeberg et al. 2008) and 0.95 (James-Belin et al. 2019) <b>SEM</b> SEM 7.1 (Thoomes-de Graaf et al. 2017), 5-7.8 weighted ave 6.4 (St-Pierre et al. 2016)	<b>Internal consistency</b> Cronbach alphas = 0.85 pain, 0.9 disability <b>Structural (factorial)</b> 2 factors 61.4% of variance <b>Construct:</b> moderate-strong strong correlates with VAS (pain levels) Moderate correlates with ROM & muscle strength (St-Pierre et al. 2016)	<b>Effect size</b> 1.21-1.64 weighted ave 1.36 (improved subjects) <b>SRM</b> 1.08-2.19 (St-Pierre et al. 2016) <b>AUC:</b> 0.81 (Chester et al. 2017)
<b>QuickDASH</b>	<b>Function Social Work</b>	<b>Likert scale</b>	8-15.9% (Mintken et al. 2009; Franchignoni et al. 2014)	<b>ICC</b> 0.82-0.94 weighted ave 0.91 <b>SEM</b> 4.8-5.51 weighted ave 5.21 (St-Pierre et al. 2016)	<b>Structural (Factorial)</b> 2 factors explained 59.1% of the variance <b>Construct:</b> Moderate correlations with SF-12 physical component, low with SF-12 mental component. Moderate correlates with ROM & muscle strength (St-Pierre et al. 2016) <b>Known group validity</b> can discriminate between individuals with different disability levels	<b>Effect size</b> 0.74-1.4 weighted ave 1.14 (all subjects) <b>SRM</b> 0.46-1.4 (all subjects) weighted ave 0.93, 1.08 (improved subjects) (St-Pierre et al. 2016) <b>AUC</b> 0.82 (Mintken et al. 2009), 0.78 (Chester et al. 2017)
<b>Constant-Murley score</b>	<b>Function Sleep Strength ROM</b>	<b>Likert scale Options/categories</b>	3-16.6, median 8.3 (Hao et al. 2019)	<b>ICC</b> 0.92 (James-Belin et al. 2019), >0.8 (Huang et al. 2015) <b>EMPRO</b> Reproducibility 70.8; Internal consistency 25 (Vrotsou et al. 2018)	<b>Construct validity:</b> moderate negative <0.5 (Huang et al. 2015)	<b>Effect size</b> 0.21 <b>SRM</b> 0.44 (James-Belin et al. 2019) <b>Longitudinal validity</b> Correlation with construct function moderate positive >0.5 (Huang et al. 2015) <b>EMPRO:</b> 83.3 (Vrotsou et al. 2018)
<b>PGIC</b>	<b>Rating of change</b>	<b>7-point Likert scale</b>	<b>Not established</b>	<b>ICC</b> 0.61 – 0.62 (test retest) Inter-rater reliability 0.62 (Bobos et al. 2020)	<b>Construct</b> -0.5-0.31 ASES (very weak to weak) Garrison et al (2012) 0.16 to -0.59 with DASH, SF-12, SPADI & PRWE (very weak to moderate) (Bobos et al 2020)	<b>Effect size</b> $r = 0.6$ Strongly correlated with GPE (Bobos et al 2020)

### **2.7.5 Methods used to enhance quality of measures**

The outcomes assessor was a clinical specialist in rheumatology<sup>4</sup> and had experience of administering the outcome measures. All outcome measures were administered face to face. The SPADI, QuickDASH and PGIC are patient rated outcome measures, and the CMS is patient and assessor rated as it includes some objective measures including ROM and strength. Objective measurements were taken as per Constant *et al.* (2008), however, the original scoring method was used for the patient rated section. The measure of abductor strength is repeated three times using a standardised test position and a spring balance to improve accuracy (A spring balance is attached distal on the forearm. Strength is measured with the arm in 90° abduction, full extension of the elbow and the palm of the hand in pronation. The patient is asked to maintain this position for five seconds. The measurement should be pain free. A score of zero is given if there is pain or if the patient cannot achieve the position) and the average is recorded. Pain-free range of movement was measured using a goniometer for flexion and abduction. Functional external rotation and internal rotation was measured as unassisted by placing the hand/thumb against the anatomic landmarks or the arm into various positions.

## **2.8 Sample size**

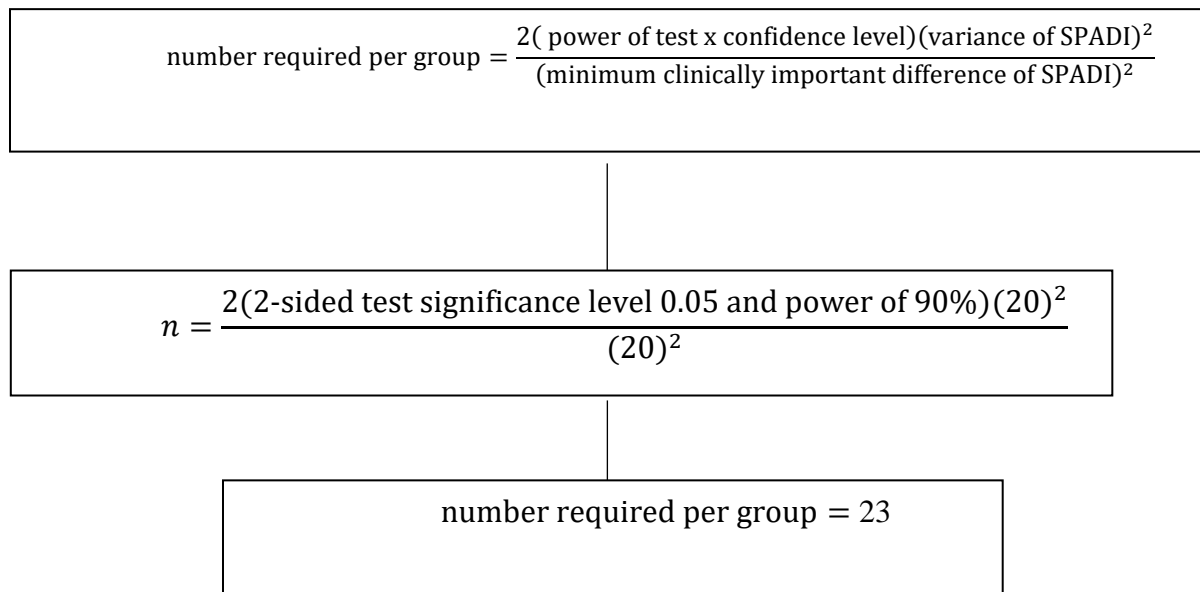
The SPADI measure was chosen as the primary outcome measure as it is a shoulder specific patient rated measure whose psychometric properties have been ascertained for the rotator cuff population and it is widely used in shoulder pain literature so comparison with other studies will be possible. In order to prevent the possibility of a type II error, a sufficiently large sample size needed to be determined. The sample size calculation for the SPADI was

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done using the power calculation for the comparison of means in two independent samples using G\*Power software (Faul *et al.* 2007). This calculation required an estimate of the variability of the SPADI and minimum clinically important change. Standard deviation for the SPADI in rotator cuff disease has previously been reported as 20 points (Granviken and Vasseljen 2015) and a change of greater than 20 points (15.4%) is regarded as clinically meaningful (Ekeberg *et al.* 2010). The significance was selected as 5% (2-sided) with a power of 90% (**Figure 5**)



**Figure 5** Sample size calculation

The sample size required was calculated as 23 for each group (total 46) and to allow for an attrition rate of 30 % (14), we aimed to recruit 60 participants. Participants were recruited in blocks of 16 and once the target was achieved recruitment continued until the last group was filled. As a result, 69 subjects were recruited over 6 blocks.

## 2.9 Consent

Once patients were screened and deemed eligible for the study, they were invited to take part in the study and given the participant information leaflet and consent form (Appendix I). Participants were informed that participation was entirely voluntary and that they were

free to withdraw at any stage without this influencing their treatment. To control for expectation bias, participants were told that it is not known which treatment is superior. In most cases consent was obtained directly after the screening. When the potential participant needed time to decide if s/he wanted to participate, s/he was given the participant information leaflet and consent form to take home. Written consent had to be given for the patient to be enrolled in the study and before randomisation and initial baseline measures were taken.

## **2.10 Randomisation Sequence generation & Allocation concealment: Detection Bias.**

Randomisation involves generating an assignment sequence which cannot be predicted and concealing that sequence until allocation occurs. Allocation concealment is essential to prevent researchers from selecting participants whose symptoms indicate that they would be most likely to react favourably to the treatment under investigation (Schulz and Grimes 2002a).

Block randomisation was used to ensure an even distribution of participants and variables to each treatment group (Roberts and Torgerson 1998) and to ensure that there were sufficient numbers of participants for the class in each block of treatment to run. For each of the six blocks of treatments, equal numbers of sealed envelopes (8 for group exercise and 8 for individual treatment) were prepared by one of the researchers delivering the group exercise intervention. The envelopes were opaque and aluminium foil was placed behind the card to ensure allocation concealment. The card on which the allocation was written was covered with carbon paper. The envelopes were shuffled and placed in a large envelope. Simple randomisation was achieved by asking a person unconnected with the trial to choose an envelope at random once a participant had consented. The participant's

name plus the next sequential study number was then written onto the envelope before it was opened (and transferred onto the card with the allocation) to prevent the consenting therapist from changing their allocation.

Participants were enrolled in the study by the screening physiotherapist when consent was obtained. They were then assigned to their intervention as described above when the envelope containing their assigned intervention was drawn at random by a person unconnected to the study the envelope was opened, and the allocation was revealed.

## **2.11 Blinding of outcome assessor: Selection Bias.**

The outcomes' assessor was a clinical specialist physiotherapist in rheumatology, who was not involved with recruitment or in delivering the interventions and was blinded to the participants' treatment allocation and participants were advised not to reveal their treatment allocation to the outcomes' assessor. It was not possible for the therapists delivering the interventions or for the patients receiving the interventions to be blinded.

## **2.12 Ethics Approval**

Ethics approval was received from the Clinical Research Ethics Committee, University College Cork: ECM3(kkk) 04/04/17 & ECM3(kk) 06/06/17. A copy of the ethics approval is contained in appendices (see Appendix K). The trial was conducted in accordance with the principles of the Declaration of Helsinki (World Medical Association n.d.).

### ***2.12.1 Trial protocol***

A pre-specified protocol (Appendix J) was submitted with the ethics application, although this protocol was not pre-published or publicly registered. In this trial all outcomes were reported as per protocol, regardless of results, and no sub-grouping was performed. Raw

data is provided in Appendix L. The trial was not registered because the trial had commenced before the investigators became aware of the requirement to register the trial.

## **2.13 Data analysis**

Outcome measures were initially recorded on paper and the results were stored securely in individual patient files in a locked cabinet together with the consent form. They were later transferred to an excel spreadsheet (Appendix L) for statistical analysis. This anonymised file was deleted from the computer and saved onto a memory stick and kept together with the patient records in a locked cabinet. All data analyses were completed using SPSS (version 26) software.

### **2.13.1 Baseline variables**

Baseline demographics and characteristics and all outcome measures were described and presented for both groups as recommended by the CONSORT Statement (Schulz *et al.* 2010) (Chapter 4). Baseline variables recorded include onset, gender, presence of diabetes, whether dominant arm was affected and previous steroid injection. As random allocation to treatment groups was used, any differences between groups at baseline have occurred by chance so statistical comparison of the two groups is unnecessary. Therefore, in accordance with CONSORT statement recommendations (Schulz *et al.* 2010), statistical comparison of baseline outcome measures or characteristics were not performed.

### ***2.13.2 Post-intervention and follow-up: Analysis of quantitative data***

Two-way repeated measures analysis of variance (ANOVA) was used for between group analysis of all continuous data (SPADI, QDASH, and CMS) using Bonferroni adjustment to adjust for multiple comparisons of change from baseline to the 3 follow-up time points (6-weeks, 12-weeks and 24-weeks). All continuous data (baseline and follow-up outcome measures) were tested by group for equality of variances and sphericity to determine whether the data complies with the assumptions of the two-way repeated measures ANOVA. Box's test for equality of variances and Mauchly's test of sphericity was performed. As the numbers in both groups exceeded 30, the central limit theorem may be applied which states that the distribution in large groups approximates a normal distribution (Kwak and Kim 2017). Therefore, the data was not checked for normality. The raw scores for the SPADI and QuickDASH were converted to a percentage. Significance for all tests was set at  $P < 0.05$ . All analyses were done according to the intention to treat principle using the last value carried forward to account for missing data.

The data from the seven-point PGIC which were collected at the 3-follow-up time-points was divided into "improvers" and "non-improvers" and percentages from both interventions compared. We defined "improvers" as participants who rated the change in their condition from baseline as "much better" or "very much better" and "non-improvers" who rated the change from baseline as "very much worse", "much worse", "slightly worse", "unchanged" or "slightly improved".

## **2.14 Summary**

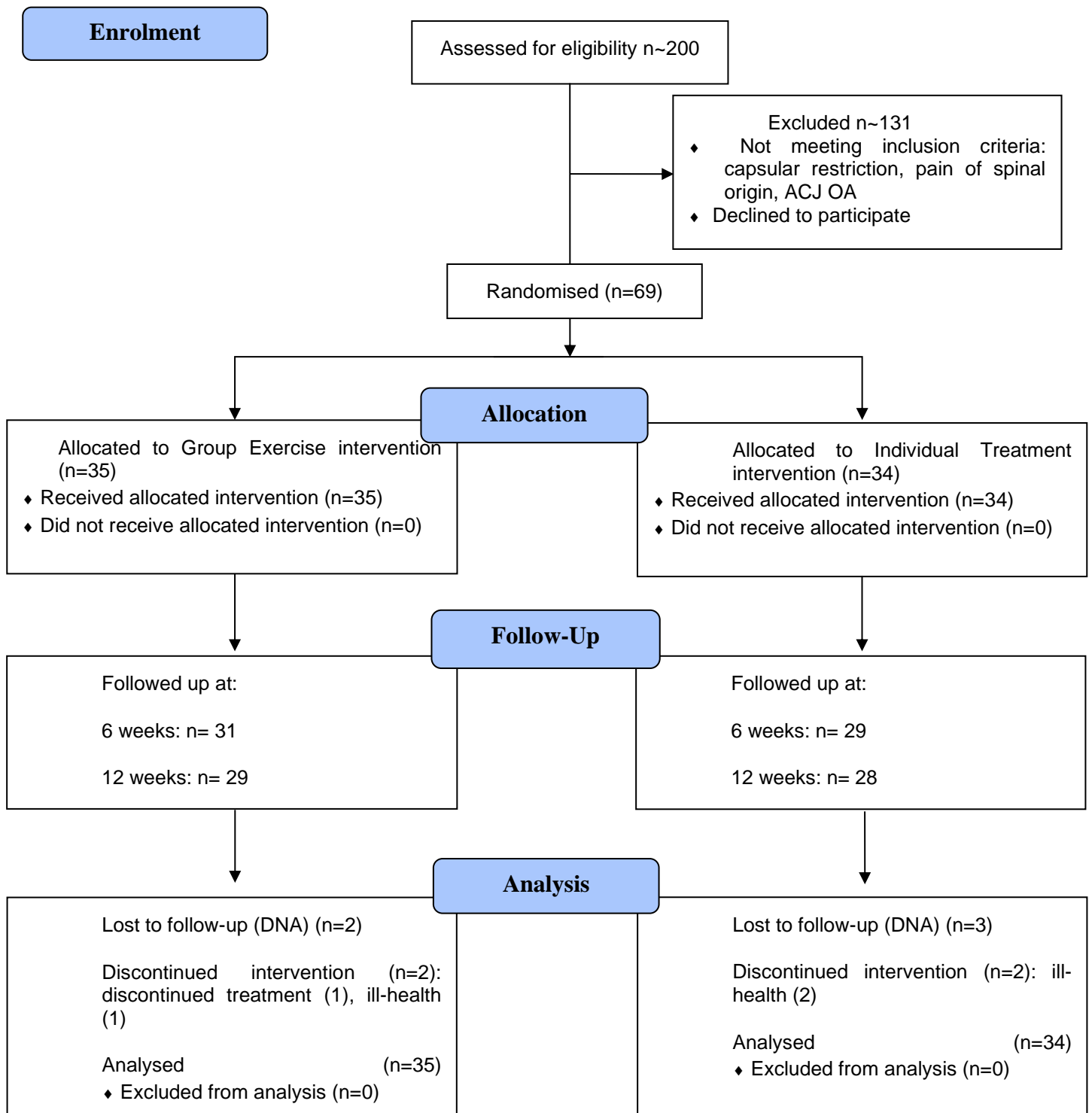
The aim of this chapter was to describe the methodology used to execute the RCT. The results of the study are presented in Chapter 3.

## CHAPTER 3 Results

### 3.1 Introduction

The objective of this study was to compare the effectiveness of group exercise with multi-modal one-to-one physiotherapy for the treatment of rotator cuff tendinopathy using the primary outcome measure, the SPADI, to assess changes in self-reported pain and disability. Secondary outcome measures used were the QuickDASH, CMS and PGIC. This chapter will begin by describing the participant flow through the study starting with the recruitment and randomisation of the participants, pre and post treatment assessments and then analysis of the data. Baseline characteristics and outcome measures will be presented for comparison. The continuous data outcome measures (SPADI, QuickDASH and CMS) were analysed to assess changes over time within and between groups. Finally, a comparison of the patients' satisfaction with treatment will be presented using a patient global rating of change outcome measure, the PGIC.

As illustrated in **Figure 6** approximately 200 patients with shoulder pain were assessed for eligibility. Sixty-nine (20 male, 49 female) consented and were randomised to either the group exercise (n=35) or the individual treatment (n=34) arms of the study. At follow-up, two from the group exercise and three from the individual treatment intervention did not complete their treatment. Two from the group exercise arm withdrew from the study, one due to health reasons and one discontinued treatment. Two from the individual treatment group withdrew from the study, both for health reasons.



**Figure 6** Consort Flow Diagram

\* Participants were deemed to have completed the trial if they completed their treatment and attended for baseline and at least one other follow up assessment.

### 3.2 Recruitment:

Participants were recruited from June 2017 to September 2018 and all follow-ups were completed by March 2019.

### 3.3 Baseline data:

Baseline characteristics are presented in **Table 4**. The table shows that both groups were similar in terms of gender proportion and age. As is typical of this patient group, a far higher proportion were female (24 out of 34 individual treatment/25 out of 35 group exercise) and this was almost equal between groups. Baseline duration (mean (SD)) of symptoms was higher in the individual treatment group at 20.5(SD 29.1) months versus 10 (SD 8.2) months in the Group Exercise group but recall of duration of symptoms is difficult and subject to inaccuracies. Approximately one-third of participants in both groups had a traumatic onset of symptoms, almost two-thirds of shoulders affected were of the dominant arm. A small proportion, five in each group, were diabetic and seven in each group had been treated with a steroid injection. These variables were very evenly distributed between the two groups.

**Table 4** *Baseline Characteristics by Intervention*

<b>Baseline characteristic</b>	<b>Group exercise n=35</b>	<b>Individual treatment n=34</b>
<b>Sex, male/female</b>	10/25	10/24
<b>Age in years Mean (SD)</b>	65.5(14.4)	63.2(16.0)
<b>Duration of shoulder pain in months Mean (SD)</b>	10.0(8.2)	20.5(29.1)
<b>Dominant shoulder affected n/total (%)</b>	22/35 (63%)	22/34 (65%)
<b>Traumatic/insidious onset</b>	11/24	8/26
<b>Diabetic: n/total</b>	5/35	5/34



<b>Injection: n/total</b>	7/35	7/34
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### 3.4 Baseline outcome measures

Means and standard deviations for the baseline outcome measures, SPADI, QuickDASH and Constant Murley Score, are presented in **Table 5**. The scores for the two groups are similar but there are slightly higher levels of pain and disability in the individual treatment group across all baseline outcome measures.

**Table 5** Baseline Outcome Measures in means (SD)

<b>Outcome Measure</b>	<b>Group Exercise</b>	<b>Individual Treatment</b>
<b>SPADI - Total</b>	50.1(22.2)	55.0(21.8)
<b>SPADI - Pain</b>	60.2(21.1)	64.8(23.4)
<b>SPADI - Disability</b>	44.1(25.2)	50.2(23.1)
<b>QuickDASH</b>	44.5(21.8)	48.9(21.8)
<b>Constant Murley Score</b>	52.6(14)	50.9(14.8)

*Scores for SPADI and QuickDASH are presented as %*

### 3.5 Attendance rates

Mean (SD) attendance rate for Group Exercise was 72.9 % (23.6) and the mean (SD) number of Individual treatment sessions attended was 4.1(2.1).

### 3.6 Within group changes

Patients in both groups were reassessed after six weeks, 12 weeks and finally at 24 weeks and outcome measures were recorded. The mean values for these outcome measures in addition to the mean differences from baseline are shown for each follow up timepoint in **Table 6**. All outcome measures demonstrate a statistically significant change from baseline at all three follow-up timepoints.

At six weeks only the Group Exercise intervention showed a clinically significant improvement in SPADI (total) scores compared to baseline as the difference in means from baseline exceeds the MCID for the SPADI, 15.4%. At 12 weeks and 24 weeks both interventions showed a clinically significant improvement compared to baseline values. The MCID for the SPADI (Pain) and SPADI (Disability) sub scores has not yet been established. The results for the QuickDASH show that only the Group exercise intervention achieved a clinically significant change at 12 and 24 weeks with an MCID of 15.9%. The Individual treatment group did not achieve a clinically significant reduction in QuickDASH scores at any follow up timepoint and the QuickDASH scores did not improve after the 12-week mark. The change CMS scores for both groups exceeded the MCID of 8.3% at all follow up time points, representing clinically significant improvement.

**Table 6** Within Group changes from baseline in means (SD)

<b>Outcome Measure</b>	<b>Group Exercise</b>	<b>Individual Treatment</b>	<b>Change from baseline: Group Exercise</b>	<b>Change from baseline: Individual Treatment</b>
<b>SPADI-Total</b>				
<b>Baseline</b>	50.1(22.2)	55.0(21.7)	—	—
<b>6 weeks</b>	34.4(25.1)	43.7(22.4)	15.7(21.0) *†	11.2(18.2) †
<b>12 weeks</b>	29.7(24.6)	37.3(25.4)	20.4(19.7) *†	17.7(22.1) *†
<b>24 weeks</b>	24.305(25.3)	35.4(25.6)	25.8(21.4) *†	19.5(19.7) *†
<b>SPADI – Pain</b>				
<b>Baseline</b>	60.2(21.1)	62.8(23.4)	—	—
<b>6 weeks</b>	38.9(27.7)	52.5(23.3)	21.3(22.4) †	10.2(20.7) †
<b>12 weeks</b>	34.8(27.3)	45.4(25.6)	25.4(23.0) †	17.4(24.4) †
<b>24 weeks</b>	29.0(28.7)	45.4(28.9)	31.2(23.6) †	17.4(25.1) †
<b>SPADI – Disability</b>				
<b>Baseline</b>	44.1(25.2)	50.2(23.1)	—	—
<b>6 weeks</b>	31.6(25.6)	39.7(22.7)	12.5(21.8) †	10.5(18.5) †
<b>12 weeks</b>	26.4(25.2)	32.0(26.2)	17.6(20.9) †	18.2(22.5) †
<b>24 weeks</b>	20.8(24.3)	29.3(25.6)	23.3(22.0) †	20.9(30.3) †
<b>QuickDASH</b>				
<b>Baseline</b>	44.5(21.8)	48.9(21.8)	—	—
<b>6 weeks</b>	30.2(22.1)	38.9(20.5)	14.3(16.9) †	9.9(17.8) †
<b>12 weeks</b>	25.6(23.0)	34.1(21.6)	18.9(17.6) *†	14.8(20.9) †
<b>24 weeks</b>	24.5(24.0)	34.6(24.1)	20.0(18.1) *†	14.3(19.4) †
<b>Constant Murley Score</b>				
<b>Baseline</b>	52.6(14.0)	51.0(14.8)	—	—
<b>6 weeks</b>	66.6(16.9)	61.6(15.7)	14.1(13.4) *†	10.6(13.1) *†
<b>12 weeks</b>	68.7(15.7)	64.8(15.2)	16.1(15.2) *†	13.9(13.2) *†
<b>24 weeks</b>	73.0(18.0)	66.8(16.1)	20.5(16.0) *†	15.8(16.6) *†

\* Clinically significant change

† Statistically significant change

### 3.7 Between Group Differences

The repeated measures mixed ANOVA was used to determine if there were any significant between group differences in the SPADI, QuickDASH and CMS at the three follow-up time points (**Table 7**). At six weeks and 24 weeks there was a statistically significant between group difference in the SPADI (Pain) in favour of the group exercise intervention,  $P=0.031$  and  $P=0.022$  respectively, with moderate effect sizes for both. There was no statistically significant between group difference at any follow-up time-point for any of the other outcome measures.

**Table 7** Between Group differences

Outcome measure	Mean Difference	Std Error Difference	Difference [95% CI]	P-value	Effect Size ( $\eta^2$ )
<b>SPADI-Total</b>					
<b>0-6</b>	4.4	4.7	[-5.0, 13.9]	0.109	0.038
<b>0-12</b>	2.7	5.0	[-7.4, 12.8]	0.214	0.023
<b>0-24</b>	6.3	5.0	[-3.6, 16.2]	0.073	0.047
<b>SPADI – Pain</b>					
<b>0-6</b>	11.1	5.2	[0.7, 21.5]	0.031†	0.068
<b>0-12</b>	8.1	5.7	[-3.3, 19.5]	0.101	0.040
<b>0-24</b>	13.8	5.9	[2.1, 25.5]	0.022†	0.076
<b>SPADI – Disability</b>					
<b>0-6</b>	2.0	4.9	[-7.8, 11.7]	0.171	0.028
<b>0-12</b>	-0.6	5.2	[-11.0, 9.9]	0.373	0.012
<b>0-24</b>	2.4	5.1	[-7.8, 12.5]	0.163	0.029
<b>QuickDASH</b>					
<b>0-6</b>	4.4	4.2	[-4.0, 12.7]	0.093	0.042
<b>0-12</b>	4.1	4.6	[-5.1, 13.4]	0.118	0.036
<b>0-24</b>	5.7	4.5	[-3.3, 14.7]	0.086	0.043
<b>Constant Murley Score</b>					
<b>6-0</b>	3.4	3.2	[-3.0, 9.8]	0.205	0.024
<b>12-0</b>	2.3	3.4	[-4.6, 9.1]	0.301	0.016
<b>24-0</b>	4.6	3.9	[-3.2, 12.5]	0.133	0.033

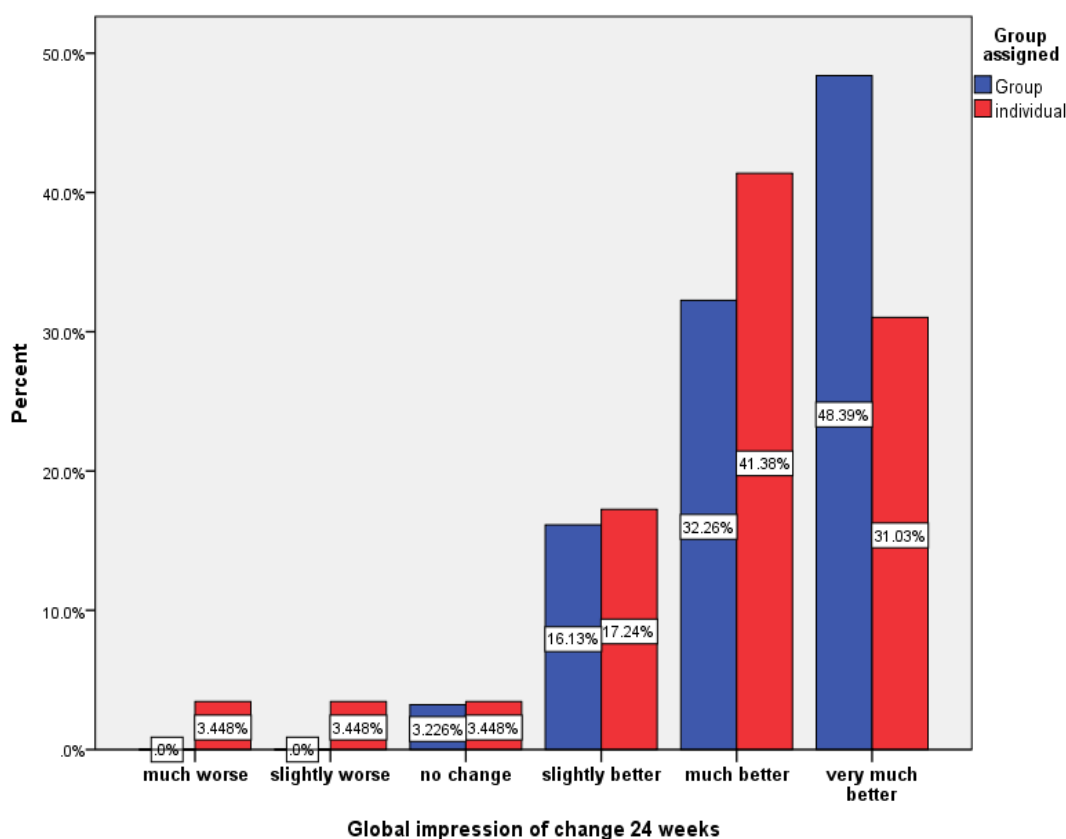
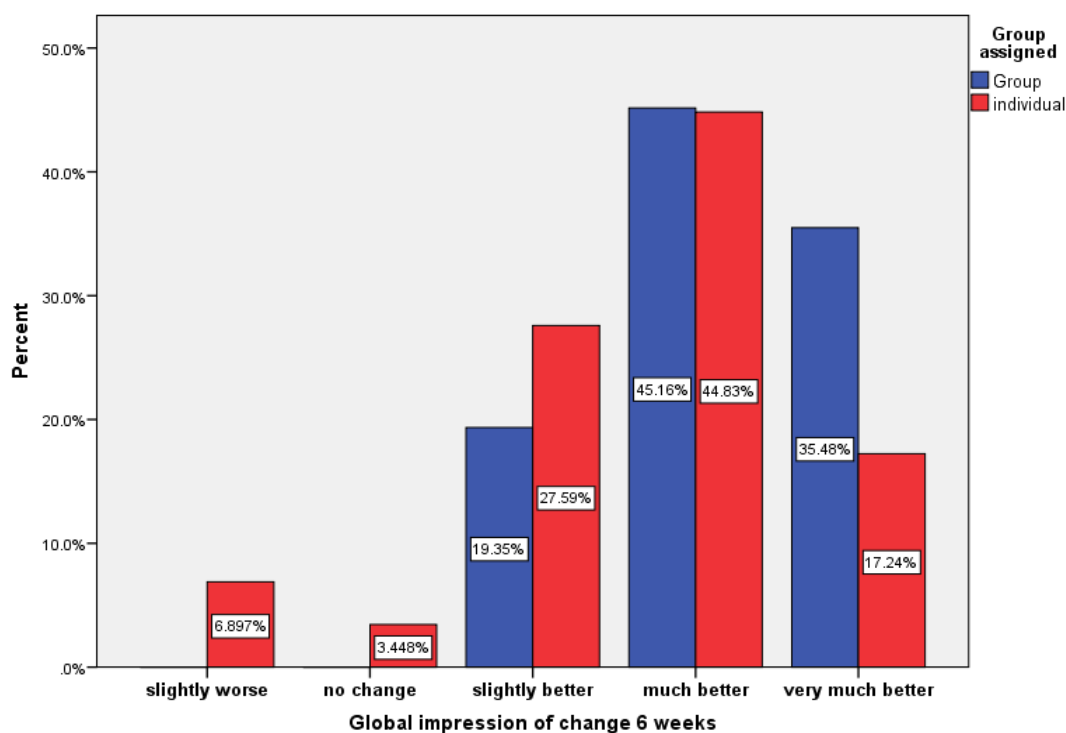
†Statistically significant difference

Effect Size Classification: Small  $0.01 \leq \eta^2 < 0.06$ , Medium  $0.06 \leq \eta^2 < 0.14$ , Large  $\eta^2 \geq 0.14$

### **3.8 Patient Global Impression of Change**

The PGIC was used to evaluate the patients' overall satisfaction with their outcome. We defined participants as Improvers (satisfied with outcome) if they rated their shoulder condition as “much better” or “very much better” and as Non-improvers (not satisfied with their outcome) if they rated their outcome as “very much worse”, “much worse”, “slightly worse”, “no change” or “slightly better”.

At six weeks, none of the participants rated themselves as “much worse” or very much worse, 80.7% of the group exercise and 62.1% of the individual treatment were “Improvers”. At 24 weeks, the same percentage of the of the group rated themselves as improved but within that a higher proportion at 24 weeks rated themselves as “very much improved” compared with at six weeks (48.4% at 24 weeks versus 35.5% at six weeks). In the individual treatment group, 72.4% rated their shoulder condition as improved at 24 weeks which was an increase of over 10% from six weeks. Similarly, the proportion of individual treatment participants who reported their shoulder condition as being very much improved at 24 weeks increased compared with at the six week follow up (31.0% up from 17.2%).



**Figure 7** Patient Global Impression of Change at 6 weeks and 24 weeks

*\*Improver= very much better, much better.*

*Non-improver= very much worse, much worse, slightly worse, no change, slightly better.*

### **3.9 Adverse events:**

There were no reported adverse effects. However, almost 7% of participants in the individual treatment arm rated their shoulder condition as slightly worse or much worse at 6 weeks and 24 weeks. None of the group exercise participants rated their shoulder as worse at any follow up time point.

## CHAPTER 4 Discussion and Conclusion

### 4.1 Aim and summary of main findings

There is strong evidence for exercise in the management of rotator cuff tendinopathy (Pieters *et al.* 2020). However, the best format for delivery of this treatment is not known. The aim of this study was to compare the effectiveness of group exercise with individual physiotherapy for the management of rotator cuff tendinopathy in primary care.

There was no statistically significant difference between the outcomes of Group Exercise and Individual treatment for the SPADI (total), QuickDASH or Constant-Murley score at any of the follow-up timepoints. However, when the SPADI was divided into pain and disability subscales as recommended by Jerosch-Herold *et al.* (2018), there was a statistically significant difference in the SPADI (Pain) at six weeks and 24 weeks in favour of the group exercise intervention.

There was also a difference in terms of the clinically significant change within the groups. The group exercise intervention showed a clinically significant change in SPADI (Total) from baseline at six weeks and continued to improve, but it was not until the 12-week follow up that the individual treatment intervention showed a clinically significant improvement. This may be because not all the individual treatment participants had completed their treatment by six weeks, but it may indicate a quicker improvement with the group exercise intervention. An early and appreciable response to treatment is deemed to be important for exercise adherence (Littlewood *et al.* 2014; Sandford *et al.* 2017) because patients may need to commit to several months of exercise (Bennell *et al.* 2010). The QuickDASH did not show a clinically significant improvement for the individual treatment group at any follow up but the group exercise



intervention showed a clinically significant improvement from 12 weeks on. An MCID of 15.9% was used to determine clinically significant change. MCIDs as low as 8% (Mintken *et al.* 2009) have been reported for the QuickDASH which would signify clinically significant improvements for both interventions at all follow-ups.

A greater proportion of participants in the group exercise arm of the study rated their shoulder condition as clinically improved at six weeks and 24 weeks compared with the individual treatment participants, 80.7% of Group Exercise at both timepoints versus 60% and 72% for Individual treatment participants at six and 24 weeks respectively. It is acknowledged that the PGIC is subject to recall bias as described in Chapter 2, nevertheless, the results still reflected a greater satisfaction amongst Group Exercise participants at these different time points. For both groups there was an increase in the percentage of participants rating themselves as “very much improved” at 24 weeks compared with the six week follow up, meaning that improvements for both interventions were not only maintained but increased.

## **4.2 Findings in relation to other research**

Our findings are broadly in line with previous research which has shown that outcomes for group exercise patients are at least equivalent with outcomes for individual physiotherapy patients with rotator cuff tendinopathy. A systematic review and meta-analysis by O'Keeffe *et al.* (2017) found no difference in changes in pain and disability when comparing exercise-based group interventions and individual treatment for patients with MSK disorders and any differences were in favour of group interventions. Russell *et al.* (2014) obtained superior outcomes with group exercise for frozen shoulder which were statistically but not clinically significant for group over individual treatment in a shorter period. An RCT by Ryans *et al.* (2020) compared six sessions of group exercise to six sessions of multi-modal individual physiotherapy for

patients with subacromial impingement syndrome and found that outcomes were equivalent. They concluded that group physiotherapy for RC tendinopathy is cost-saving when compared with individual treatment and does not impact negatively on health-related quality of life. To our knowledge, this is the first study to demonstrate a statistically significant between-group difference in favour of group treatment for RC tendinopathy in primary care.

RCTs have compared group (supervised) exercise with home (unsupervised) exercise for frozen shoulder and non-traumatic shoulder pain patients and found that outcomes were significantly better in the group exercise interventions (Russell *et al.* 2014; Asensio-Garcia *et al.* 2018). Interestingly, a study by Granviken and Vasseljen (2015) which compared ten sessions of supervised exercise with home exercise noted no difference between groups in SPADI scores. However, the adherence rates for both interventions were very high at greater than 80%, in fact, adherence in the home exercise group was actually higher, in contrast to most other research into exercise adherence (Sluijs *et al.* 1993). It is noteworthy that the patients' rated change (improvement) was higher amongst the supervised exercise group which may suggest a greater satisfaction with outcome due to the influence of the patient-therapist relationship.

## **4.3 Explanation of findings**

### ***4.3.1 Self-management***

The success of any MSK intervention is linked with adherence to an exercise programme (Pisters *et al.* 2010). This is especially true for treatment of rotator cuff tendinopathy where exercise is recommended as a first-line treatment. Although not recorded in the individual treatment intervention of this study, non-adherence to a

home exercise programme may be as high as 70% (Sluijs *et al.* 1993). In this study, participants allocated to the group exercise intervention did their exercises twice weekly in the class (negating the requirement to do them at home while attending the class). If the goal is to transition to longer term self-management, then key components of the self-management approach are adherence to a home exercise programme and a belief in one's ability to cope with setbacks and relapses.

Frequent and more intensive monitoring facilitates exercise adherence (Sandford *et al.* 2017). The regular contact between therapists and participants provided by the class afforded therapists the opportunity to put strategies in place which facilitate a transition to long term self-management. Self-management interventions should involve more than simply a transfer of knowledge (Jonkman *et al.* 2016). Bassett (2015) talks about “bridging the intention-behaviour gap” with behaviour change interventions/strategies. The frequency of the class permitted therapists to prepare participants psychologically by educating them of the benefits of exercise with evidence-based information, responding to their concerns about exercise (exercise causing harm for example), tackling any unhelpful beliefs and teaching coping strategies for dealing with setbacks and relapses as they arise.

If patients are unsure if they are doing their exercises correctly, they begin to question themselves and lose confidence which affects their capability to perform the exercises and their motivation to exercise (Hall 2020). Self-efficacy is one's belief in their ability to carry out a given task or activity and it has been cited as a correlate of exercise adherence (Sluijs *et al.* 1993) and a predictor of outcome (Chester *et al.* 2018; De Baets *et al.* 2019). The class develops exercise self-efficacy by offering modelling, constructive feedback, experience of success and vicarious experience (components of the Bandura model of self-efficacy (Bassett 2015)). The design of the group exercise

intervention allowed participants to practice their exercises within a supportive environment where they received constructive feedback on their exercise performance but also the independence to develop self-regulatory skills such as sensing the onset of fatigue and monitoring pain levels, thus improving their exercise self-efficacy. Positive and constructive feedback from therapists enhances adherence (Sluijs *et al.* 1993; Sandford *et al.* 2017) by positively influencing psychological and physical capability and thus motivation (Hall 2020).

O'Keeffe *et al.* (2017) proposed that the success of group interventions over individual treatment may be due to the fact that group interventions spend more time on evidence-based effective treatments such as exercise and education whereas individual treatment time may be used less effectively for passive treatments which don't facilitate transition to self-management. Analysis of the treatment provided in individual sessions revealed that strengthening exercises were the most used treatment modality followed by education and advice on self-management. Myofascial trigger point therapy via manual release (20 participants) and dry needling (7) was also widely used which concurs O'Keefe's contention, however, there is evidence for the use of manual therapy in conjunction with resisted exercise (Pieters *et al.* 2020). Russell *et al.* (2014) suggested that group interventions create less dependency than individual therapy by fostering behaviour change via self-management.

#### **4.3.2 Biopsychosocial Considerations**

Shoulder pain affects every aspect of life (Lowe *et al.* 2014; Gillespie *et al.* 2017; Page *et al.* 2019; Maxwell *et al.* 2020). A recent review by Maxwell *et al.* (2020) highlighted the biopsychosocial nature of shoulder pain and the need for interventions to be targeted towards biopsychosocial factors rather than just structural. Previous studies have mentioned the invisible nature of shoulder pain as there is no obvious outward

signs meaning that sufferers often lack support from co-workers and acquaintances (Jones *et al.* 2013). Group interventions may be a source of peer support, where contact with others with the same condition validates their pain experience (Russell *et al.* 2014; Sandford *et al.* 2017; Barrett *et al.* 2018; Ryans *et al.* 2020).

#### **4.3.3 Exercise**

There is inconclusive evidence about what type of exercise is best (Chapter 1) for RC tendinopathy. A recent systematic review recommended exercise as a first-line intervention for RC tendinopathy (Pieters *et al.* 2020) and there is some evidence (uncertain clinical benefit) for progressive resisted exercise (Naunton *et al.* 2020).

As described in the methods section, the “Group Exercise” exercise component consisted of RC, scapular and lower limb resisted exercises. These were progressive and designed to induce change by overload (Lombardi Jr *et al.* 2008). Progression was determined on an individual basis. For some individuals, they were progressed to a level they would not have pushed themselves to at home. The design of the class allowed for modification of certain exercises to suit individuals. The pain monitoring system (Thomee 1997) was used when exercising which recommended that only low levels of pain were tolerated. Some studies for rotator cuff related shoulder pain, for example Littlewood *et al.* (2016), had a requirement that exercise was painful. Although this was avoided in this study to avoid latent pain onset and negative associations with exercises as pain can be a barrier to exercise adherence (Jack *et al.* 2010; Sandford *et al.* 2017). A systematic review (Smith *et al.* 2017) found that patients who experienced pain when exercising had a small but significant benefit in function in the short term over those who avoided pain when exercising encouragement to exercise further into pain, may function to reduce fear avoidance behaviours with a type of pain exposure therapy.

Lower body exercise was included as many upper body activities involve a transfer of force from the lower limbs via the trunk to the shoulder. Richardson *et al.* (2020) demonstrated that incorporating the kinetic chain during rehabilitation lowers the demand on the rotator cuff. Full body exercise and core exercises to optimise kinematics and load transfer should be considered. This may also be a more functional way of exercising.

One criticism of group interventions has been that they provide a ‘one size fits all’ approach (Sandford *et al.* 2017). Individualised care is important for patient satisfaction (Hush *et al.* 2011). The circuit design of the class and the ratio of two therapists to eight participants allowed for individualisation and tailoring of the participants’ exercise programme and education on load management and progression. Any potential problems with the exercise programme, e.g. unacceptable pain levels, inappropriate loads, could be addressed while the patient was exercising.

One unique feature of the group exercise intervention was that patients weren’t expected to exercise at home. The reason behind this was that we wanted them to learn correct motor patterns under supervision to optimise the benefits of the exercises so that when they had finished the block of classes they would be proficient in the exercises and be convinced of the benefits of exercise through positive experiences of exercise.

#### ***4.3.4 Individual treatment intervention***

Analysis of the individual treatment intervention revealed that similar to the group exercise intervention exercise, advice and education formed the mainstay of treatment provided. While all participants in this arm of the study received a home exercise programme, some of these programmes consisted of range of movement or stretching

exercises i.e. types of exercise for which there is no evidence in the management of rotator cuff tendinopathy (Pieters *et al.* 2020). Yet, participants in this arm of the study experienced comparable outcomes to participants of the individual arm of the study.

One explanation may be that therapists were free to choose from a wider variety of interventions which addressed other contributing factors such as neck or thoracic pain, and although research has shown there is questionable additional benefit for some treatments (see Chapter 1), they were arguably able to provide a more tailored/ patient-specific treatment which is advocated by Klintberg *et al.* (2015).

The influence of the patient-therapist relationship on outcome in physiotherapy settings has long been recognised (Hall *et al.* 2010). There is the potential for developing a better relationship between a patient and a therapist in individual treatment sessions as opposed to in a group. In the group exercise intervention, the class was run by three different therapists so although they had more therapist contact time it is doubtful that a close relationship was formed. When therapists have the opportunity to assess the patient and carry the treatment out to its conclusion, they naturally obtain a deeper, more nuanced understanding of the patient's often complex presentation.

There may be psycho-social elements which are difficult to address in a group setting as some patients may not feel inclined to open up or speak freely in a group setting. These may be more appropriately addressed in an individual treatment scenario.

Other qualitative research (Barrett *et al.* 2018) has revealed that some participants are concerned about keeping up with the group. While the design of our intervention should minimise the potential for this to occur due to the circuit structure of the class, some patients may not be suited to a group class.

#### 4.3.5 Cost saving

In primary care as in all areas of the public health service, there are always pressures to make services as streamlined and cost efficient as possible. Our study revealed an average of 4 individual treatments per patient which compares favourably with group treatment, offering good value for money.

One of the proposed benefits of group interventions is that they may be more resource efficient. In our study, group participants received 12 one-hour sessions of physiotherapy input with two therapists to eight participants. Individual treatment participants received an average of four sessions, range one to ten. This reflects usual care for musculoskeletal conditions in primary care (May 2003). Although the group exercise intervention in our study was not cost saving in terms of physiotherapy input, Carr *et al.* (2005) found decreased use of secondary healthcare for chronic low back pain treated in a group versus individual physiotherapy with group participants more likely to seek conservative treatment and individual treatment participants seeking more invasive and specialist interventions in subsequent care episodes.

Ryans *et al.* (2020) showed a cost saving for group over individual physiotherapy and equivalent outcomes for both interventions in patients with subacromial shoulder pain. In that study, group participants received six sessions with a supervisory structure of three patients to one therapist and all individual treatment participants received six sessions. The study included an economic evaluation of all healthcare costs with the major savings resulting from physiotherapy. Ryans *et al.* (2020) study may have overestimated the cost-saving for the group. In our study, participants in the individual treatment group received an average of four treatments however the range of treatment sessions received was one to ten. This means that some participants in the individual treatment arm of the Ryans *et al.* (2020) study may have received more treatment than



they required and some not enough. Our study more accurately reflects normal practice. In accordance with the Carr *et al.* (2005) trial non-physiotherapy healthcare usage was higher in the intervention group of Ryans *et al.* (2020) trial. Given the additional benefits of the group in terms of facilitating transition to long-term self-management, the extra cost in terms of physiotherapy time might be money well spent.

Alternatively, the group format could be adapted to make the group class more resource efficient i.e. the group could consist of ten instead of twelve sessions and one therapist to eight patients after the first four sessions. In this study, patients were not expected to exercise at home arguing that correct form was best. It may be that perfect performance of exercise is not that important, and patients could be encouraged to exercise at home between sessions leading to a quicker improvement and reducing the need for 12 sessions.

#### ***4.3.6 Attendance***

Abramson (2018) evaluated completion rates in his class for subacromial pain and found that younger patients and those from more deprived areas had poorer attendance rates. He recommended that these patients should therefore be seen individually. Adherence to the group in the present trial was in line with other studies at 75% and Ryans *et al.* (2020) found similar attendance between group and individual treatments. So, concerns about low attendance rates for a group are not justified.

#### ***4.3.7 The role of treatment preference***

If participants had a preference for one treatment over the other, this may have influenced their performance introducing performance bias. Patients are known to improve more when they receive their preferred treatment (Carr *et al.* 2005; Moffett *et al.* 2005). The influence of treatment preference on outcome is unknown as we did

not ascertain participant preferences at baseline. There is strong evidence that expectation of improvement is a strong determinant of outcome in shoulder pain patients (Dunn *et al.* 2016; Chester *et al.* 2018). As noted by Barrett *et al.* (2018), a “hands off” treatment such as an exercise class has the potential to jar with patients’ expectations of physiotherapy which has traditionally been associated with “hands on” treatment. However, some participants in that qualitative study, which explored patients’ experiences of participating in a shoulder class, expressed a preference for a class. To date there has been little research into patient preference for treatment in physiotherapy. Treatment preferences are likely to be formed previous experience (Bernhardsson *et al.* 2017). Regardless of the strength their preferences, patients appreciate being involved in discussions and decision-making about their treatment (Bernhardsson *et al.* 2018)

## **4.4 Strengths and limitations**

Study design was a strength of trial, a number of measures were taken in the design of the trial to minimise the risk of bias. It is important to minimise bias in clinical studies because it affects the reliability and validity of study results and can therefore have significant clinical consequences (Smith and Noble 2014). In the section below, different types of bias are described as per the Cochrane Collaboration (2011) and an explanation of how they were addressed in the study is provided.

### **4.4.1 Bias**

Selection Bias is biased allocation to interventions due to inadequate concealment of allocations prior to assignment. In order to avoid selection bias, allocation to intervention groups was randomised and the allocated intervention was concealed using opaque sealed envelopes.

Performance bias occurs due to knowledge of the allocated intervention by participants and personnel during the study resulting in systematic differences in the care that is provided or exposure to factors that may have influenced outcomes other than the intervention itself. Masking of participants and personnel can help to control performance bias. It was not possible to blind participants or personnel in this study to the intervention being received or delivered, however, participants were informed prior to their participation in the study that it was not known which intervention was superior and personnel involved in delivering the interventions were only involved with delivering one intervention.

Detection bias signifies systematic differences between groups in how outcomes are determined. Blinding (or masking) of the outcome assessor may reduce the risk that the knowledge of which intervention was received, rather than the intervention itself, affects the outcome. In this study, the same outcome assessor completed the outcome measures for both groups and was blinded to the allocation of the participants. Furthermore, participants were instructed not to reveal their treatment allocation to the outcomes' assessor. Although some of the outcome measures were self-rated and may be subject to bias if a participant has a particular treatment preference, they are the standard method of assessment.

Attrition bias is a type of selection bias that arises from systematic differences in the way participants are lost from a study. Losses to follow-up and reasons for withdrawal from the study were accounted for (Chapter 3). Most withdrawals were for medical reasons and the rate of dropouts was equal across both arms of the study.

Selective reporting of outcomes bias: Selective reporting of a particular outcome measurement or analysis. This usually results from a desire for results to support vested interests or to be sufficiently notable to warrant publication. A pre-specified

protocol was submitted with the ethics application, all outcomes were reported as per protocol, regardless of results, and no sub-grouping was performed.

Other strengths were the use of a valid and reliable primary outcome measure whose psychometric properties had been determined including an MCID which allowed for calculation of an adequate sample size. The sample was representative of the population in terms of age and gender mix. Very good retention of participants was attained, in contrast to some other RCTs on rotator cuff tendinopathy (Littlewood *et al.* 2016; Ryans *et al.* 2020). An adequate length of follow-up time was included to ascertain if the effects of treatment were maintained in the longer term. Finally, an intention to treat analysis was used which is considered to be best practice as it is the most conservative estimate of change.

Limitations were a lack of a control group (no intervention) as natural recovery, may have played a part (Morton and Torgerson 2005). However, participants had already had the condition for a significant length of time, median of 9 months, so any natural recovery should have already occurred. It was not ethical to deny treatment to patients referred to physiotherapy.

Although reasons for exclusion and failure to consent were documented, the exact number of patients screened, and numbers not admitted to study were not recorded. It may have been useful to know what proportion of shoulder pain patients referred to primary care physiotherapy have RC tendinopathy, the proportion of patients not consenting and reasons for not consenting. It is not known whether patients refused to consent because they preferred individual treatment, or because they had difficulty attending a group intervention for 12 sessions.

Adherence to exercise after the class finished was not recorded. However, the best method of recording exercise adherence has not been established. Diaries are a common method of measure adherence to home exercise programmes (Jack et al. 2010). However, this can generate inaccurate data due to poor compliance with real-time diary completion and recall accuracy (Stone et al., 2003 cited by (Jack et al. 2010)).

O'Keeffe *et al.* (2017) recommended that exercise programmes should be administered according to FITT (frequency, intensity, time and type) principles. Although the method of progression was clearly outlined in the group exercise intervention, it was difficult to determine exercise progression in the individual treatment intervention due to limitations in documentation i.e. increases in repetitions or sets may not always have been documented and simply recorded as exercise programme being reviewed to give feedback on exercise performance.

Exercising with high loads and allowing more pain in line with parameters mentioned in Chapter 1 may have led to better outcomes. Although lower limb exercises were included in the class, the inclusion of full body exercise and core exercises to optimise kinematics and load transfer might be beneficial (Richardson *et al.* 2020). Although resistance type exercise was used, we could have used higher loads and fewer reps to avoid tendon fatigue. There were ten exercises included in the circuit. Perhaps we could have used fewer exercises and progressed the exercises toward more functional exercises related to patient specific goals.

We did not set a lower limit on the SPADI as an inclusion criterion, perhaps we should have excluded patients with very low scores as it is difficult to appreciate a difference with treatment with very mild pain or disability.

## **4.5 Recommendations for clinical practice**

Exercise-based group classes with education on pain mechanisms, lifestyle factors and efficacy of progressive resistance exercise which are adequately staffed to allow for individual interaction and tailoring of exercise progression should be offered as part of a range of interventions for RC tendinopathy.

Where possible it may be beneficial to group similar types of patients together i.e. younger/older. When patients see others they identify with being successful (with exercise) this can act as a motivator. However, this may be difficult to implement in practice unless there are large numbers of patients suitable for the class.

Patient specific goal setting was not formally done as part of the class and the outcome measures used to evaluate the success of an intervention don't necessarily measure the things that are important to patients (Gardner *et al.* 2015). The patient specific functional scale is recommended as it is patient specific and led and facilitates them to identify their functional goals.

## **4.6 Recommendations for future research**

Subgrouping participants by age, severity of symptoms or duration of symptoms to determine which patients benefit most from group and which do better with individual treatment would provide better guidance for clinical practice.

This study, which was carried out at one primary care centre, has shown that group exercise is at least as effective, if not more effective, for patients with RC tendinopathy treated in primary care. A multi-centre study with greater numbers of participants would add to the evidence base and increase the generalisability of these results.

## **4.7 Conclusion**

This study shows that group exercise is as effective as individual multi-modal physiotherapy for the management of rotator cuff tendinopathy in primary care. There were no differences in outcome between groups for most outcome measures, however the pain subscale of the SPADI shows that there was a significant between group difference at both six and 24 weeks in favour of the group exercise intervention. The Group Exercise arm of the trial achieved a clinically significant improvement in the SPADI at six weeks indicating a quicker response to treatment than the individual treatment intervention. The Group Exercise intervention also showed that a higher proportion of group exercise participants were satisfied with the change in their shoulder condition at the six and 24 week follow ups.

In primary care, physiotherapists can be assured that both group and individual treatment approaches are effective allowing them to recommend both treatments and permitting patients to make informed choices for treatment. Therapists can confidently offer a class with this study adding to the growing evidence base for the effectiveness of group treatment which also addresses the biopsychosocial aspects of care as outlined above and facilitates a transition to long-term self-management.

## CHAPTER 5 Qualitative Study

### 5.1 Introduction

Exercise-based treatment for the management of rotator cuff tendinopathy is widely accepted as the most effective first line choice (Kuhn 2009; Hanratty *et al.* 2012; Abdulla *et al.* 2015). Cognitive reassurance, including education about the condition, prognosis, treatment options and goal setting (Pincus *et al.* 2013) is also recognised as central to management of the condition to address unhelpful beliefs and to create a therapeutic alliance between the patient and therapist (White *et al.* 2020). It is possible to deliver both key components in either a group setting or through individual treatment sessions.

Group interventions may be as effective and more cost effective than one-to-one physiotherapy. A systematic review by O'Keeffe *et al.* (2017) found that exercise-based group interventions were at least as effective as individual physiotherapy in managing musculoskeletal conditions. Russell *et al.* (2014) found superior outcomes with group exercise compared to one-to-one physiotherapy for frozen shoulder patients and a recent study by Ryans *et al.* (2020) comparing group treatment with individual treatment in the management of sub-acromial impingement syndrome found no difference in outcomes between groups. Studies evaluating the cost effectiveness of group interventions have established that not only do they cost less than one-to-one physiotherapy, but recipients of group-based care also seek less secondary care (Carr *et al.* 2005; Ryans *et al.* 2020). “Meeting patients’ expectations and preferences” (Laerum *et al.* 2006, p38) is the essence of patient-centred care and patients like to be involved in decision making about their treatment (Laerum *et al.* 2006; Hush *et al.* 2011). Therefore, it is important to gain insight into their feelings and preferences for



formats of treatment delivery. Yet, patient preference in MSK physiotherapy is an under-researched area (Bernhardsson *et al.* 2017).

Traditionally, physiotherapy is seen as a ‘hands on’ treatment (Littlewood *et al.* 2014) and as Barrett *et al.* (2018) noted treatment in a class may conflict with patient’s expectations. An exploration of health professionals’ experiences of managing RC tendinopathy report that, in their opinion, many patients may have unhelpful beliefs and attitudes about treatment preferring passive interventions rather than committing to exercise regimes (White *et al.* 2020). It is recognised that identifying and matching patients’ expectations is important for clinical outcomes (Littlewood *et al.* 2014). Barrett *et al.* (2018) explored shoulder pain patients’ experience of participating in a group and found that participants were positive about their group experiences, reporting support, motivation and learning from peers, a sense of mastery over the exercises and the transfer of knowledge between therapist and patient. While not a key focus of the study, some participants reported a preference for group over one-to-one physiotherapy, while others expressed a preference for one-to-one treatment based on previous positive experiences of ‘hands on’ treatment. This study builds on Barrett’s study by exploring the preferences for and experiences of both group and one-to-one physiotherapy participants with the treatment they received for rotator cuff tendinopathy in a primary care setting. Whether there was a difference between recipients of the two interventions in terms of exercise adherence post treatment and in participants’ confidence with performing their exercises and managing the condition is also of interest.

## **5.2 Method**

The aim of this study was to qualitatively explore experience of attending either individual or group physiotherapy for the management of RC tendinopathy in primary

care. This study expands on the findings of Barrett *et al.* (2018)'s study by interviewing participants from both group and individual treatment to elucidate preferences for modes of treatment delivery and differences between groups in exercise confidence following treatment for rotator cuff tendinopathy in a primary care setting.

### **5.2.1 Study Design**

A qualitative study was conducted using semi-structured interviews to explore shoulder patients' experiences of and preferences for either group or individual treatment in the management of rotator cuff tendinopathy.

### **5.2.2 Description of interventions**

All participants had previously taken part in a randomised controlled trial (RCT) which had compared group exercise with individual treatment sessions for the management of rotator cuff tendinopathy in Blackrock Hall physiotherapy Department, a primary care outpatient department which receives musculoskeletal referrals from GPs. Participants were randomised to receive their treatment in either a group exercise class or at individual treatment sessions. Baseline measurements of pain and disability were taken before treatment commenced, then repeated at 6 weeks, 12 weeks and 26 weeks. Group exercise subjects attended a 1-hour circuit class twice a week for 6 weeks. The class comprised of rotator cuff, scapular and lower limb strengthening with an education component. The treatment and number of appointments that the subjects in the individual treatment sessions received was decided by the treating therapist. Treatment generally consisted of exercise and advice/education but was not limited to these treatment components, the mean number of treatment sessions was four. Interviews took place approximately one year after treatment had concluded. While this time period may have impacted on recollection, it had the advantages of providing

an indication of longer-term adherence to exercise not previously measured in the RCT and obtaining a sense of participants' lasting impression of the treatment they had received.

### ***5.2.3 Participants & recruitment***

Six subjects from the individual treatment arm and five from the group exercise cohort were invited to participate out of a total of sixty who completed the RCT (sixty-nine were recruited). This seemed a feasible number of interviews for the interviewer (CM<sup>5</sup>) to complete in the time available (two days). Participants were sampled purposively to get a balance of gender and age from both arms of the RCT which was representative of the participants in the larger study (***Table 8***). Participants were invited to participate by phone. A researcher (DK) phoned selected eligible participants and gave them a brief description of the study. Interested potential participants were sent a patient information leaflet and consent form and were asked to sign and return the form once they had the opportunity to read it and ask questions. Once the signed consent form was received participants were enrolled in the study and contacted again to arrange a time that was convenient for the telephone interview. All eligible subjects who were invited consented to participate in the study, however, one participant had to withdraw prior to the interview due to a family bereavement and another candidate of similar profile was invited to participate and gave written informed consent.

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<sup>5</sup> PhD candidate undertaking qualitative research into shoulder pain

**Table 8** *Demographics of participants*

<b>Participant</b>	<b>Group/1:1</b>	<b>Gender</b>	<b>Age</b>
<b>1</b>	1:1	Female	74
<b>2</b>	1:1	Female	62
<b>3</b>	1:1	Male	71
<b>4</b>	Group	Female	47
<b>5</b>	Group	Male	80
<b>6</b>	Group	Female	86
<b>7</b>	Group	Female	57
<b>8</b>	1:1	Female	66
<b>9</b>	Group	Female	46
<b>10</b>	1:1	Female	72

#### **5.2.4 Interviews & data collection**

Telephone interviews are a flexible, cost effective method of collecting qualitative data from interviews (Novick 2008). They are comparable to face to face interviews in terms of depth and richness of data collected (Sturges and Hanrahan 2004) and have the advantage of more anonymity, decreased social pressure and allowing interviewees to remain in their own environment leading to more relaxed interviews where participants speak more openly (Novick 2008). The telephone interviews were selected as the researcher who undertook the interviews was based in a different location to the participants. It was felt that participants having to travel to a location for a face to face interview might also be a barrier to recruitment. Interviews lasted between 10 and 18 minutes (mean 13.66min). A researcher (CM), who was an experienced musculoskeletal physiotherapist with a knowledge of qualitative research but not involved in the RCT, carried out all the interviews. This was to reduce bias and to allow participants the opportunity to speak freely and candidly about their experiences. An interview guide (Appendix P) to help steer the interviews was devised by the first author (DK) a physiotherapist who was involved with the RCT. Nineteen questions designed to elicit information of interest to the research team were generated to investigate participants experiences of treatment received for rotator cuff

tendinopathy. The questions were amalgamated into six key topics with prompts by grouping together questions that were in a similar vein. This was done to allow participants to develop their answers to allow sufficient depth of answers and to keep the interviews focussed. A short summary of the treatment received by all participants plus an outline of the RCT including a description of the group exercise class was sent to the researcher conducting the interviews. All telephone interviews were recorded using a Dictaphone and transcribed verbatim by DK.

#### ***5.2.5 Ethical considerations***

Ethical approval was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals, University College Cork, Reference number: ECM4 (ii) 19/04/19 (Appendix N). Written informed consent was obtained from the participants prior to their enrolment in the study (Appendix O). Participants were informed that they were under no obligation to participate and were free to withdraw at any time. Transcripts of interviews were anonymised and were labelled participant 1-10. Audio recordings and transcripts of interviews were saved on a memory stick, deleted from the laptop on which they were processed, and the memory stick was kept secure in locked filing cabinet in the primary care centre for a period of seven years. The data was not encrypted, however, only the first author (DK) had access to data and all other recordings and copies of the transcripts were destroyed.

#### ***5.2.6 Data Analysis***

Qualitative description is the method of choice where straight forward descriptions of experiences are required to answer questions that are relevant to clinicians (Sandelowski 2000). Thematic analysis (TA) using Braun & Clarke's 6 phase approach (Braun and Clarke 2006) was used to analyse the data. It is suited to

the novice qualitative researcher as it is a relatively easy and quick to learn compared to other methods of qualitative data analysis and it provides results which are accessible to a wide audience (Braun and Clarke 2013). This approach, which involves searching across the entire dataset to find repeated patterns of meaning (Braun and Clarke 2006), was used.

The aim of the study was to explore participants' experiences and perceptions, in keeping with this, an essentialist framework of analysis was used to make sense of participants experiences, preferences and perceptions. With this type of analysis, a straightforward relationship between language and meaning is assumed and the themes are more data-driven i.e. they depend on the data as opposed to the research questions (Braun and Clarke 2006). At each stage of the process the first author (DK) and AM<sup>6</sup>, who is an occupational therapist, met to review progress. The first author became very familiar with the data by reading through the interviews several times. A sample interview was coded separately (AM & DK) and codes were compared to check that they were broadly similar. Then all interviews were coded by the author and codes were agreed with AM. Coding focussed on semantic meaning which reflects the explicit meaning of the data. Codes and corresponding data extracts were entered into an Excel spreadsheet to collate the data. Similar codes were amalgamated, and the codes were organised into groups. Preliminary themes were generated from the groups of codes by studying associations between them and organising them around a central concept to give an internally coherent account of the data. Themes were then reviewed and refined through regular meetings and discussions between AM and DK, and data extracts were chosen and used to illustrate the themes.

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<sup>6</sup> AM is an academic, lecturer and MSc supervisor

### **5.2.7 Trustworthiness**

A number of strategies were used to ensure trustworthiness of the data and analysis (Krefting 1991; Shenton 2004). As the author had been involved with delivering one of the interventions in the RCT, the interviews were conducted by a researcher whom the participants had never met and who had no input or involvement with the RCT. This was to ensure confirmability or objectivity (Shenton 2004) and to avoid socially preferred responses. Participants were encouraged to be honest with their opinions and this was aided by the neutrality of the independent researcher who conducted the interviews. The interviewer never revealed her profession to avoid participants delivering socially preferred responses (Krefting 1991). The codes and themes were agreed by a researcher (AM) who was independent of the RCT.

## **5.3 Results**

Three themes were generated from the data: “what patients value from treatment”, “engagement with exercise during and after treatment” and “characteristics of a successful outcome”.

### **5.3.1 *What patients value from treatment.***

This theme explores what participants reported were useful aspects of either format of treatment. This included support from the therapist or peers, receiving an explanation about their condition, feedback on their exercise performance and advice on how to manage their condition.

Participants expressed a satisfaction with the level of support experienced both with group and individual treatment (IT). Helpfulness and pleasantness of therapists was appreciated by both sets of participants.

*P5 “each of the physios, they were very, very nice, very attentive, pleasant people, so, no bother working with them, like, y’know and they were very professional at their work, y’know”*

Group participants reported that they received plenty of supervision and individual attention from the therapists.

*P7 “if we were doing anything wrong in the class they were always there to correct; Oh, like when, em, when they’re talking to you, they always made time to talk to you individually, y’know”.*

They described enjoyment of being in class

*P7 “It made it kinda more fun. Y’know, it made it more sociable”*

*P6 “I got to know the people after the second week... it was kinda becoming a happy place in the end, y’know”*

and the value of interacting with patients experiencing similar shoulder problems,

*P7 “Cos nobody kind of understands unless they’ve gone through it themselves”*

Group participants also discussed receiving peer support and how within the group setting they had opportunities to learn from one another.

*P6 “you learn from each other aswell, y’know...sometimes I’d stall because I’m aged now like, I’d stall as to what I was going to do next, y’know. But you could look at somebody else and [at what] they’re doing.”*

IT participants were also satisfied with the level of support received in this format of treatment delivery and felt that they received “100% attention” (P3). In the IT format,



participants reported feeling that the therapist was fully focussed on them and their problem with one participant describing it as being more personal

*P1 “Ah the one to one I suppose was more personal... when you’re going into these things you’re a bit anxious but when you’ve got the regular meeting with them, y’know, you kinda have a thing between ye then, she’d know you well”;*

Although all IT participants said that initially they had no preference for either IT or group, one participant aired a concern that strong personalities in a group might “*take over a bit*”(P3), and another reported that they would “*feel under pressure to maybe try a bit maybe harder than I was capable of doing*”(P2). When asked which they would prefer if they needed treatment again, all IT participants expressed a preference for individual treatment. However, these concerns were not raised by any of the participants who participated in the group format. One participant in the group format did acknowledge potential challenges “*if people were maybe a bit objectionable or maybe if the physios hadn’t the right kind of approach*” (P5).

Participants from both groups valued being given explanation for what was going on with their shoulders even if their understanding of the shoulder condition was vague or incorrect. It validated their pain, armed them with an explanation that they could give to others and made them feel justified

*P7 “they just kind of like explained exactly what was going on with my shoulder and that kind of made [me] understand it better... ya it was very helpful to find out.... so you felt that that kind of a deeper understanding”*

There was a lot of appreciation for advice/education especially on how to manage the condition. Both sets of participants described the value of feedback from the therapists

in terms of ensuring that they were doing the exercises correctly and encouraging them to progress or do a little more.

*P6 “but like goin to the clinic and doing the exercises and them tellin me what to do gave me good confidence to keep goin with it, y’know”.*

*P3 “I suppose the advice, maybe do a little extra. I wasn’t doing it maybe because I was afraid I’d hurt myself, but I think I was advised, y’know do a little more, that it’s not going to do any damage to put your arm over your head or something like that”.*

### **5.3.2 Engagement with exercise during & after treatment**

This theme reveals patients’ attitudes to and beliefs about exercise, their reported adherence and motivations to exercise and what patients see as facilitators of exercise. Participants from both treatment groups reported a strong positive belief in exercise and in the main were convinced that exercise was key to recovery

*P3 “I suppose when I wasn’t doing the exercises it was painful, before I started down there. So, for me, the exercise was the cure”*

Participants from both formats also reported that they would choose to recommence their exercises should their symptoms recur.

*P6 “what the physio did for me was that I can go straight away, I’ve still all my elastic bands hanging on the doors and I can still do my bits now, if it does start”; P7 “if I feel it getting anyway.... bit sore again, I just go back and do the exercises so and that seems to help”; P8 “I’m not doing them at the moment, I do it when it’s inclined to get sore again....At the first indication that it is getting sore, and it seems to help”.*

Participants described referring to their exercise manuals and printed exercise sheets when they returned to exercising after a break, highlighting the value of printed

material. However, for the most part, adherence to the exercise programme waned once the symptoms (pain) eased and the shoulder was good. While participants described varying degrees of compliance, only one participant reported that he was motivated to exercise in order to prevent the symptoms recurring. This was despite an admission that they were educated by the therapists about the recurrent nature of tendinopathy and advised to continue with exercise. However, it does seem that there was an intention to continue with exercise

*P5 “You know what like, tis a case of the road to heaven is paved with good intentions, y’know...And eh, you mean to do it and like 101 things you mean to do”*

Laziness, meaning a lack of motivation due to lack of symptoms, was cited as the reason for discontinuing exercises

*P2 “I was just dead lazy really (laughter) and then when nothing’s bothering me I go oh that’s grand so I forget about it then”*

One participant expressed a fear of doing harm with exercises and decided it was better to P5 *“leave well enough alone like y’know. If it comes back, ok do the exercises but don’t do the exercises and maybe bring on the problem again”*

Despite the positive attitudes to exercise, it was acknowledged that there are some challenges associated with exercise. Some participants described that exercise could be painful, not that easy to do (strenuous) and that they needed to push themselves. However, the regular practice provided by the class (group) was described as a facilitator

*P4 “once I kind of got into the routine of the exercises it was grand, you kind of got faster at it then each time that you went in...it’s so much easier kinda going into a class and you don’t have to think about it”*

Participants from both arms of the trial reported confidence in their ability to perform their exercises. Participants from the group exercise group remarked on being taught well, the feedback received from the therapists led to proficiency confidence with doing the exercises participants valued the opportunity to practise their exercises and knowing that they were doing it right

*P6 “sometimes if you go, maybe like as I was doing first like one to one go in and they show me what to do, you come home then you’re tryin to guess.....But when I went back to do the class like it was a different thing because, em, like you were there for an hour anyway.... I mean you definitely know what to do when you’re coming out”*

*P6 “it was very beneficial to me like that I was doing something that I knew I was doing right”*

Whereas 1:1 participants didn’t offer any reasons/evidence for their confidence in their ability to perform the exercises but mentioned that they could refer to their exercise sheets to guide their exercises.

Individual treatment participants also reported that they felt confident in doing their exercises citing access to exercise sheets as facilitating exercise. While the majority of group participants felt the 12-session format was sufficient, one participant expressed a desire for the class to continue.

### ***5.3.3 Characteristics of a successful outcome***

In this theme participants identified a successful outcome as an improvement in function and an acquired confidence in their ability to manage their condition independently. This was common to both group exercise and IT interventions. Functional limitations were described as both a major motivator to seek treatment and an important indicator of successful treatment and were independent of how treatment

was delivered. Participants tended to describe their improvement in terms of the things they can now do without thinking about it. They described having awareness of their shoulder condition limiting activity before treatment and reduced or no awareness of limitation after treatment.

*P4 “Lifting or carrying or washing or anything... even just putting my arm into a sleeve and stuff like that, I don’t even think about it now anymore whereas I did before”.*

Feelings or expectations about the success of the treatment was seen to be influenced by previous experience. One participant described a fear of losing function as she had a bad outcome with her other shoulder but also remained hopeful due to previous positive experience with physiotherapy

*p6: “I was hoping that twas going to do wonders for me really...when my own doctor decided to send me to physio, I was kind of y’know, I was glad about that aswell, y’know, it was a way out”*

Another feature typical of a successful outcome was the acquired ability to independently manage the condition post treatment and an absence of expectation or need for further treatment

*P4 “I mean it’s up to yourself really isn’t it, they were very good at explaining everything they gave us the tools, they gave us the books, they gave us the pulley thing and the band, the resistance bands and everything so I suppose it really is only up to yourself. You can’t have people checking up on you, everybody’s all grown up”*

Conversely, one participant from the group intervention described a lack of ability to manage her pain and felt that she needed further treatment by a physio to help her and described searching for remedies to relieve her pain

*P9 “Well if someone suggested further treatment that would alleviate the pain, I’d be up for further treatment, to ease the pain”* this was a characteristic of a poor outcome.

Participants from both groups described an ability to self-manage their condition with increased awareness of aggravating factors and successful management strategies such as activity modification or load management. They reported a reduced fear of using the arm or doing harm with activity and a confidence in the robustness of their shoulders. Symptoms, when they recurred, were described as fleeting, non-threatening and the participants felt that they were armed with the knowledge/tools to manage them.

*P8 “I’m aware of, I can stop even before it’d start now;*

*[CM] Do you feel overall more confident managing your shoulder as a result of that treatment that you had?*

*Oh, I do, because number one is knowing what to do about it”.*

## **5.4 Discussion**

There is evidence that group formats are as effective (Chapter 3) and more cost-effective than individual physiotherapy (Carr *et al.* 2005; O’Keeffe *et al.* 2017; Ryans *et al.* 2020). However, patient preference needs to be considered to ensure patient-centered care is followed and an effective and productive partnership with the patient is established. The results show a satisfaction with both formats of treatment delivery.

### **5.4.1 Theme 1: What patients value from treatment.**

Previous research shows that participants’ satisfaction with treatment is strongly influenced by the interpersonal aspects of care – including the traits of the physiotherapists (Hush *et al.* 2011, O’Keeffe *et al.* 2016). Helpfulness and friendliness

of the therapists, making time to speak to participants individually and approachability was frequently highlighted as positive aspects of treatment throughout the interviews. IT participants valued the relationship with their therapist and the focus on them and their problem and feared that this would be lost in the class format. However, this was not evident in interviews from class participants. Group participants described ease of access to the therapists and adequate supervision. This is important because a systematic review by Hush *et al* (2011) highlighted that the process of treatment delivery (including adequate follow up) was also important for patient satisfaction. The class may allow for more frequent contact with the therapist all be it in the group setting. Individualisation of treatment is important for patient satisfaction (O’Keeffe, 2016). One criticism of class-based treatment is that it runs the risk of being a “one size fits all approach” (Sandford *et al.* 2017). Therapists in this study were able to tailor the treatment within the class setting by making time to speak to patients individually, addressing their concerns and adjusting their exercise programmes accordingly.

Participants did not describe a clear initial preference for one treatment over the other. A study by Bernhardsson *et al.* (2017) investigated patient preferences for physiotherapy and found that although patients like to be involved in decision-making about their treatment, the extent to which they wished to be involved varied and the overarching theme was one of trust in the competency of their therapist. They also noted that patient preferences and expectations are formed by previous experience. So, it is not surprising that in our study when patients had positive experiences of IT physiotherapy they reported that if they required further treatment, they would prefer individual physiotherapy. Peer support, positive interactions with other sufferers and peer learning was described previously as a benefit of group treatment (Barrett *et al.* 2018). This was also referred to by our participants but was not quite as evident in this study. Perhaps this was because of the circuit format of the class which meant that

patients exercised individually and interacted with each other less. This format, however, allowed for more direct supervision by therapists and retained the benefits of the therapist-patient relationship.

Laerum *et al.* (2006) states that patients need to be seen, heard and believed. Hidden suffering with shoulder pain has been previously described in qualitative research. Patients described receiving less sympathy because their suffering was not evident to observers. They also describe a lack of understanding from work colleagues, acquaintances and healthcare professionals. (Jones *et al.*, 2013). This is in spite of the fact that shoulder pain sufferers describe it affecting all aspects of life and feeling that is more disabling than back pain or mobility problems as the shoulder is used for all tasks Lowe *et al.* (2014). Participants in this study valued being given an explanation of their shoulder condition that they could understand and that would help them explain it to others. Spending time with patients who are experiencing similar difficulties is valuable and may also explain why empathy in healthcare professionals is so highly regarded.

Education and advice were considered highly beneficial. Participants valued advice on appropriate levels of activity, being encouraged to do more and on how to manage their condition. In their study, Barrett *et al.* (2018) found that even though education wasn't formally part of their intervention, patients nevertheless developed an understanding of their condition and how to manage it. O'Keeffe *et al.* (2016) report that although patient education is seen as important by patients, physios did not refer to its importance for interaction. Therefore, it is important to highlight this finding as positive interactions between patients and therapists under-pin patient satisfaction and outcome. On the on contrary, a recent qualitative study by White *et al.* (2020) exploring health professionals experiences with managing RC tendinopathy found that



they prioritised providing education and clarifying unhelpful beliefs about treatment, pain and structure. They regarded education as important to foster adherence because exercise-based management of RC tendinopathy requires a considerable commitment. However, clinicians expressed a lack of confidence in their ability to educate their patients having had little or no formal training in doing this.

#### **5.4.2 Theme 2: Engagement with exercises during and after treatment**

A strong belief in exercise and efficacy of same was evident from both sets of participants throughout the interviews. Patients credit exercise with being key to their recovery and the management strategy they would turn to first if symptoms were to recur. Although adherence to the home exercise programme is desirable in the longer-term for prevention of recurrent shoulder problems, most participants in this study stopped exercising once their symptoms resolved. However, this was not described as a conscious decision, more due to a lack of motivation when symptoms resolve. Sandford *et al.* (2017) similarly found that poor exercise adherence was associated with forgetfulness and a lack of motivation. Previous research around exercise adherence found that patients are motivated to exercise by symptoms/pain and higher levels of disability but are not motivated to exercise for prevention (Sluijs *et al.* 1993; Sandford *et al.* 2017). However, in common with Sandford *et al.* (2017) most participants in this study showed a willingness to restart them when prompted by the return of symptoms which they report is facilitated by access to equipment, booklets/exercise sheets and the competence to do the exercises.

Participants in this study described possessing exercise self-efficacy – a confidence in one’s ability to perform the exercises correctly (Sluijs *et al.* 1993). Exercise self-efficacy correlates with exercise adherence (Sluijs *et al.* 1993) and group participants report that it was enabled by regular practice in the class and the feedback received so

that they knew that they were doing it right. Barrett *et al.* (2018) likewise reported that group participants had gained a sense of mastery of the exercises. However, the challenges associated with exercise were acknowledged by most participants. Pain with exercise, finding exercises strenuous and not that easy to do were recognized as negatives of exercise. Pain that worsens with exercise can be a barrier to exercise adherence (Jack *et al.* 2010). However, tailoring of the exercise programme and education about acceptable levels of pain helped patients to overcome some of these difficulties and group participants remarked that the structure of the scheduled class made it easier to comply with the exercises.

#### **5.4.3 Theme 3: Characteristics of a successful outcome**

Earlier qualitative research exploring patients' experiences rotator cuff related pain found that it affected all activities of daily life (Gillespie *et al.* 2017). Similarly, Lowe *et al.* (2014) found that simple daily activities such as washing and dressing, lifting, carrying, reaching, filling a kettle or driving became either impossible or very difficult to do. Participants in our study also described a limitation of everyday activities as a motivator to seek treatment. An ability to do these activities more easily also characterised a successful outcome. This emphasizes the need for therapists to link treatment with patient-identified goals including activities recognised as being important for the patient. This is supported by the literature. In clinical practice outcome measures, pain ratings and objective signs such as range of movement and strength are used to measure the success of treatment. However, changes in these measures may not represent an improvement which matters to the patient. As Stevens *et al.* (2018) states that it is essential to determine patients' specific treatment goals in order to provide patient-centred care. The importance of functional goals which are meaningful and relevant to the patient has long been recognised (Randall and McEwen

2000; Melin *et al.* 2019). A study which investigated patient-led goal setting in chronic low back pain patients (Gardner *et al.* 2015) found that 77% of patient identified goals were functional goals and none of patient goals were related to pain or intervention satisfaction/improvement levels. Schoeb *et al.* (2014) recommends that goals should be agreed in collaboration with patients as they may not know what an achievable goal is.

Lowe *et al.* (2014) described symptomatic rotator cuff tear patients being overwhelmed by the shocking nature of pain and sleepless nights, affecting concentration, mood and social interactions. Participants from this study described having acquired a sense of control and an ability to manage their condition by being able to recognise aggravating factors and modifying activity accordingly - “*Knowing what to do*”. Participants reported this one year after completing their treatment. Sandford *et al.* (2017) found when exploring barriers and enablers to exercise adherence that participants reported an increased feeling of control and being able to manage their condition through improved knowledge. Jonkman *et al.* (2016) states that self-management incorporates not just a transfer of knowledge but also teaching self-monitoring and problem-solving skills that engages patients in their own care. Participants from both groups also described being less fearful of using the arm and being able to stop the pain before it starts by having developed an appreciation of load management demonstrating successful self-management in action.

#### ***5.4.5 Considerations for practice***

The results of the study show that patients expressed no initial preference for either format. As mentioned above, patients trust in their therapists and if the reasons for recommending a class are outlined and patients are reassured by the positive empirical data regarding the equivalence of group and interventions physiotherapy interventions

for shoulder pain (Russell *et al.* 2014; Ryans *et al.* 2020), patients can collaborate in joint decision-making regarding their treatment options. These finding align with previously published literature (Barrett *et al.* 2018). However, it should be acknowledged that participants in the present study had previously consented to taking part in an RCT which meant that they were unable to choose which treatment they received.

Negative aspects of the group format or fears about same (strong personalities taking over, pressure to keep up with the class, one size fits all) can be avoided by having patients exercise individually and at their own pace in a circuit-style class layout. Although the consensus was that exercise and advice on self-management were the most beneficial aspects of treatment, a small number of participants (one from each group) referred to the beneficial effect of “hands on” treatment or a desire for access to some especially for relief of symptoms. Where services allow, it may be useful to offer these patients one or two sessions of multi-modal individual treatment before sending them into a group.

Support both from the therapist and from peers was highlighted in this study as being important to patients. It is therefore important to maximise opportunities for one-to-one interaction in a class settings by the therapist making time to speak to patients individually and to create opportunities for the patients to interact e.g. in the class evaluated in the RCT patients were buddied-up with another patient when being shown exercises in the initial class. It is possible to retain the positive aspects of individual treatment (i.e. patient-therapist relationship) in a group format.

Patients in this study and consistently throughout the literature (Laerum *et al.* 2006; Hush *et al.* 2011; O'Keeffe *et al.* 2016; Bernhardsson *et al.* 2017) have referred to the importance of being given an understandable explanation of their condition and how

to manage it. While the education does not need to be delivered in a formal way (Barrett *et al.* 2018) it is important that patients are given a satisfactory explanation of their problem and advice on how to manage it i.e. how to recognise aggravating factors and on how to increase activity through load management. Patients in our study referred to the value of printed material especially for exercise adherence so it is important to provide them with clear instructions with diagrams or videos to refer to.

The importance of functional, collaborative goal setting was evident from the way in which patients consistently described their improvements in terms of the things they could do which were previously limited and frustrating. As most commonly used outcome measures used to guide and measure the success of interventions do not reflect what is important for patients (Gardner *et al.* 2015), a tool such as the Patient Specific Functional Scale, a patient-led outcome measure that assist patients with identifying functional goals and measuring change (Gardner *et al.* 2015) may be useful.

#### ***5.4.6 Limitations & strengths of study***

The main limitation was the length of the interviews which averaged 13 minutes and, in some cases, resulted in superficial answers. This is almost certainly because interviews were done one year after treatment had concluded contributing to recall problems. Some closed and leading questioning by the interviewer resulted in short answers to certain questions. However, the time lapse gave an insight into exercise adherence and outcomes in the longer term and the participants' lasting impression of treatment received.

The sample size was small with only 10 participants and results from one site limit the transferability of the findings. However, the results from this primary care site in Cork,

which has both an urban and rural catchment, concur with Barrett's previous study, on the whole, lending more weight to those findings. Participants were representative of the population under investigation i.e. primary care patients, ranging from mid-40s to mid-80s comprising more women than men and a range in severity of condition.

Interviews were transcribed by the researcher who coded interviews and analysed the data, resulting in intimate knowledge of interviews and greater fidelity to the essence of the interviews.

## **5.5 Conclusion**

The results of our study indicate that patients are satisfied with both formats of treatment delivery with both groups reporting positive experiences. Preferences for a format, when they exist, may be influenced by previous positive experiences of treatment. Appreciation by participants for support from therapists and other patients was a dominant theme. Participants from both treatment groups describe positive beliefs about the effectiveness and value of exercise as a management strategy for RC tendinopathy. Education and explanations about the condition, how to recognise aggravating factors and to manage it consistent with a self-management approach are skills that are important to patients. The results indicate that patients from both groups developed a confidence in self-management with reduced sense of helplessness which is consistent with self-efficacy. Finally, the importance of identifying functional goals in collaboration with the patient is highlighted.

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## **APPENDICES**



## Appendix A



### CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	i-iii
<b>Introduction</b>			
<b>Background and objectives</b>			
	2a	Scientific background and explanation of rationale	30
	2b	Specific objectives or hypotheses	33
<b>Methods</b>			
<b>Trial design</b>			
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	33
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
<b>Participants</b>			
	4a	Eligibility criteria for participants	34
	4b	Settings and locations where the data were collected	36
<b>Interventions</b>			
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	36-43
<b>Outcomes</b>			
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	43-51
	6b	Any changes to trial outcomes after the trial commenced, with reasons	46
<b>Sample size</b>			
	7a	How sample size was determined	51-52
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
<b>Randomisation:</b>			
<b>Sequence generation</b>			
	8a	Method used to generate the random allocation sequence	53
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	53
<b>Allocation concealment mechanism</b>			
	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	53-54
<b>Implementation</b>			
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	53-54
<b>Blinding</b>			
	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	54

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	56
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	57-58
	13b	For each group, losses and exclusions after randomisation, together with reasons	57-58
Recruitment	14a	Dates defining the periods of recruitment and follow-up	59
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	59
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	60-65
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	66
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	78-81
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	83
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	68-78
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	Appendix J
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

## Appendix B



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

Physiotherapy Department,

PCCC North/South Lee

HSE South

Blackrock Hall Primary Care Centre

Blackrock Avenue

Skehard Road

Cork

Ph: 021 4233148

Dear Dr \_\_\_\_\_,

We are doing a study in conjunction with a Clinical Specialist Physiotherapist from the South Infirmary and UCC looking at the physiotherapy management of rotator cuff tendinopathy in primary care. The aim of the study is to compare one to one usual care physiotherapy to a six week exercise- based group intervention (12 sessions).

We are looking for subjects with rotator cuff tendinopathy, with or without imaging, with a history of lateral arm pain. Please see the inclusion and exclusion criteria below.

### **Inclusion Criteria:**

- Lateral arm pain not extending below the elbow
- Trauma or insidious onset
- Evidence of tendinopathy, partial or full thickness cuff tear on MRI/US

### **Exclusion Criteria:**

- Patient unwilling to participate / requests individual treatment
- Patient under the age of 18
- History of upper limb fracture in previous 6 months
- History of shoulder surgery in previous 6 months
- History of shoulder instability
- Diagnosed with frozen shoulder
- Cervical pain with radiculopathy & hard neuro signs ( repeated cervical movement affects shoulder pain or range of movement, paraesthesia, numbness, true weakness)

- Massive irreparable cuff tear

The patients will be screened for suitability, assessed by a blind assessor and then randomised into either the class based intervention or the usual care group. They will be then re-assessed at 6 weeks, then 3 months later and 6 months later.

We would be grateful if you would consider referring on any patients, either currently on your caseload or presenting to you in the coming weeks and months, who have a valid medical card and who fit the above criteria. Patients who do not participate in the study will be offered physiotherapy as usual.

Please contact us on 021-4233147/8 if you would like any more information or if you would like to discuss the suitability of any patients.

Yours sincerely,

Deirdre Kiely, Karina Teahan & Sinead Lynch

Primary Care Physiotherapy

Blackrock Hall Primary Care Centre

## Shoulder screening form

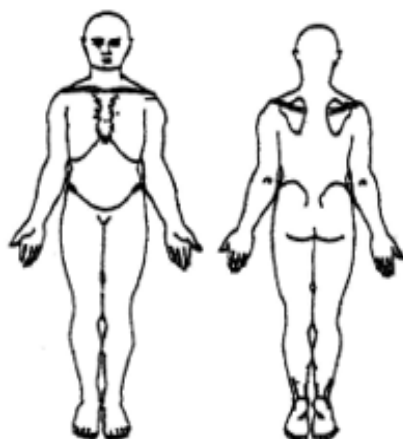
NAME: .....DOB.....

Initial Assessment Date: ..... Informed Consent given: ☐ DNA Policy:



Site of pain

Left / Right handed



Areas of pain, P1, P2  
Current NRS: /10  
Worst NRS: /10

Pins & Needles  
Numbness

24 Hour Pattern:

PC: Lateral Arm Pain (not below elbow)

HPC: Trauma/Insidious

Time since onset (in months):

Social History:

Aggs:

Eases:

Special Questions:

Investigations & result: X-ray:  
MRI:

Diabetes Y/N Smoker Y/N

PMH:

Meds:

Exclusion Criteria:

- Patient unwilling to participate / requests individual treatment
- Patient under the age of 18
- History of upper limb fracture in previous 6 months
- History of shoulder surgery in previous 6 months
- History of shoulder instability
- Diagnosed with frozen shoulder
- Cervical pain with radiculopathy & hard neuro signs (cervical repeated movement testing affects shoulder pain +/- ROM, paraesthesia, numbness, true weakness)



## Appendix C

### OBJECTIVE ASSESSMENT

0 Tender

X Hypo-mobile-stiffness

### POSTURE / OBSERVATION



Dermatomes: Right NAD ☒ Left NAD ☐

Myotomes: Right NAD ☐ Left NAD ☐

Reflexes (name)

Neural Tissue Test:

Cervical Spine: AROM

Thoracic Spine: AROM

SHOULDER	AROM		PROM	
	<u>Left</u>	<u>Right</u>	<u>Left</u>	<u>Right</u>
<u>Flexion</u>				
<u>Abduction</u>				
<u>HBB (MR)</u>				
<u>HBH (LR)</u>				

Resisted Grade & Pain		
	<u>Left</u>	<u>Right</u>
<u>Flexion</u>		
<u>ABD</u>		
<u>LR</u>		
<u>MR (Lift off)</u>		

### Rotator Cuff Impingement Tests:

Hawkins Kennedy	+ve / -ve
Empty Can ( <u>Jobe's Test</u> )	+ve / -ve
Neers	+ve / -ve
Painful Arc	+ve / -ve
Resisted lateral Rotation	+ve / -ve

Analysis:

Physiotherapist PRINT NAME

Signature

Date





## Appendix D

### Shoulder Class

(Impingement/Tendinopathy)

Name:

DOB:

	Class 1: Date:	Class 2: Date:	Class 3: Date:	Class 4: Date:	Class 5: Date:	Class 6: Date:
1. Weighted Pulley						
2.External Rotation (bed→cable)						
3. Bell Ringer (T/B)						
4.Extension (T/B)						
5.Serratus Anterior (crook→punches→4 point)						
6.Shoulder Retraction (swimming)						
7.Adductor Squeeze						
8.Step ups						
9.Shoulder shrugs						
10.Exercise bike						

## **Shoulder Class**

(Impingement/Tendinopathy)

Name:

DOB:

	Class 7: Date:	Class 8: Date:	Class 9: Date:	Class 10: Date:	Class 11: Date:	Class 12: Date:
1. Weighted Pulley						
2.External Rotation (bed→cable)						
3. Bell Ringer (T/B)						
4.Extension (T/B)						
5.Serratus Anterior (crook→punches→4 point)						
6.Shoulder Retraction (swimming)						
7.Adductor Squeeze						
8.Step ups						
9.Shoulder shrugs						
10.Exercise bike						

## Appendix E

Exercise Name	Muscles Targetted	Contraction Type	Description
	<i>Upper Limb</i>		
Weighted Pulley	Supraspinatus/superior cuff	Eccentric progressing to concentric/eccentric	Full-can eccentric elevation in the scapular plane progressed but adding a hand weight
External rotation Bed/Cable	Infraspinatus/superior cuff	Eccentric if irritable progressing to concentric/eccentric	<p>Subject is side lying with towel between arm and trunk to prevent compensatory shoulder movements, elbow flexed to 90° subject performs external rotation with or without a hand weight. If irritable may start with eccentric phase only</p> <p>May be done in standing holding onto cable from Lojer© pulley system</p>
Bell-ringer	Latissimus dorsi  Middle & Lower Trapezius	concentric	Subject is standing and from a position of abduction a Theraband© which is secured at the top of a door is pulled into adduction through a range of 120-90°. The arm is passively raised by the recoil of the Theraband© while the subject maintains scapular control.
Theraband© Extension	Rhomboids/posterior deltoid/anterior cuff	Concentric/eccentric	Subject is standing in front of Theraband© or Lojer© pulley system. Shoulder in 80° forward flexion, neutral rotation, subject performs bilateral shoulder extension with elbows extended

Serratus punches	Serratus anterior	Concentric/eccentric	Subject is lying supine with shoulder in 90° forward flexion, shoulder girdle protraction is performed. May be progressed with a hand weight
Prone retractions	Lower trapezius	Concentric/eccentric/isometric/motor control	Subject is lying prone with arms held by side, neutral rotation, subject concurrently retracts and depresses shoulder girdle and holds for 10 seconds. May progress to extending shoulders 2" off plinth.
Shoulder Shrugs	Upper trapezius	Concentric/eccentric	Subject stands with shoulders in 30° shoulder abduction, neutral rotation and elbows extended. Subject elevates the shoulder girdle whilst maintaining the shoulder abduction
Adductor squeezes	Latissimus dorsi/pectoralis major	Isometric	Subject is standing with a pillow between arm and trunk with shoulder in neutral rotation, elbow extended. Subject performs isometric shoulder adduction for 10 seconds.
	<i>Lower limb</i>		
Step ups	Gluteus maximus/quadriceps	Concentric/eccentric	Subject stands in front of 8" (standard) step. Places one foot on the steps and steps up and back with the other leg to perform hip and knee extension.
Exercise bike	Glut max/quads/hams	Concentric/Cardio-vascular	Subject does 4 minutes on exercise bike at constant "somewhat hard" or intervals of 30 seconds alternating between easy and hard.

## Appendix F

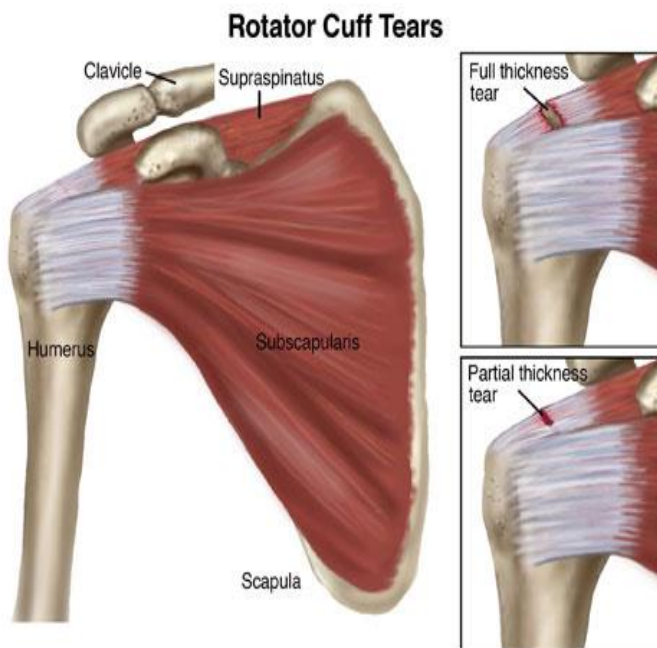
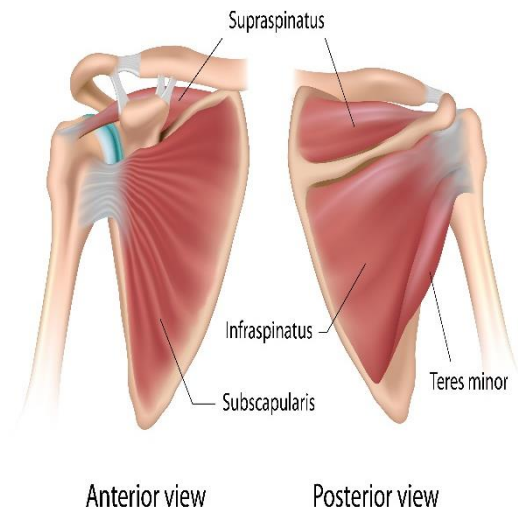
### What is the Rotator Cuff?

The shoulder is a ball and socket joint consisting of a large ball and a small socket, because of this it is dependent on a group of muscles called the rotator cuff for stability. They form a sleeve between the ball and socket providing stability and also helping to move the arm.

Shoulder pain is very common and the most common form of shoulder pain arises when there is a problem with these tendons.

### What causes problems with the Rotator Cuff?

There are a number of different terms used for rotator cuff problems. Tendinitis, tendinopathy and rotator cuff impingement are all common terms used to describe problems within the rotator cuff tendons.



***Tendinopathy:*** Occurs when the tendon has to cope with more load than it can manage. The amount of load the tendon can cope with will depend on what it is used to doing. For example a sportsperson/carpenter who is used to using their shoulder on a daily basis may be able to cope with large loads without any problem, yet in an older person who is not as physically active a small change in load (e.g. painting a ceiling) may be enough to irritate the tendon.

***Tears:*** Are most common in people over 40. They often result from trauma such as a fall on the shoulder or outstretched arm. Tendons can be partially or fully torn. Persons who tear their tendon may have a background of tendinopathy. Tears of these tendons are common as we age - it is possible to have a tear of the rotator cuff tendon and not have any shoulder pain.

### **What do the scan findings mean?**



**Imaging findings such as tendon tears and bursal thickening** (sometimes diagnosed as bursitis) **are just as common in people with no shoulder pain, as they are in people with shoulder pain.**

**This can also be the case even in elite international level athletes, and tennis players, and baseball pitchers. The tears don't stop these athletes functioning at an incredibly high level.**

**Getting better usually has got nothing to do with 'fixing' what was found on imaging, and in most situations, you should not**

**worry about what the imaging has found.**

### **Tendons can become aggravated by:**

- A sudden change in activities i.e. taking up new activity especially an overhead one such as tennis or swimming especially when you haven't been very active (using your arms), painting a ceiling or washing all the windows
- A sudden jerk when lifting or catching
- A fall
- Gradual aggravation of the tendons over a period of time especially when you do a manual job or one that involves repeated or prolonged overhead work



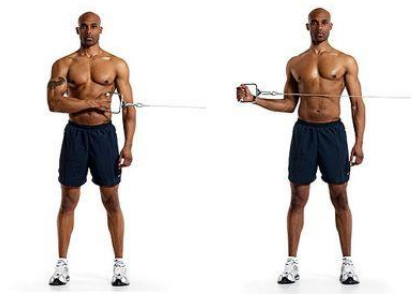
## What are the common Signs and Symptoms?

Shoulder pain is the most common symptom. You may notice pain on certain movements such as putting your hand into the sleeve of your coat or reaching up overhead (e.g. to a high cupboard). Some people may have difficulty with overhead movements because of weakness. It is also common to have pain at night if you lie on the injured shoulder. The pain tends to worsen over time if you continue to use the shoulder as normal.



## Management will involve:

1. Resting from/stopping some of the aggravating activities such as overhead activities, heavy lifting or lying on that side. This might mean moving objects placed on a high shelf to a lower position.  
Sleeping on your back with a pillow supporting the arm or a rolled-up towel under the arm to it keep away from your side.  
If you can't stop sleeping on the affected shoulder, try positioning a thin tempura (memory foam) pillow under the sheet. Tendons don't like compression
2. Do not stop moving your shoulder altogether as it will stiffen up. It may help if you can improve your posture in sitting or when doing activities.
3. You may need to take some painkillers or a course of anti-inflammatories to control the symptoms. It is useful to make a note of how much medication you are taking/need to take. Ice is an anti-inflammatory and can be used up to 3 times daily (10min on, 10min off, 10min on).
4. Some people may need an injection if night pain is a problem. If your doctor decides to give you an injection, please inform your physiotherapist in advance, as this will affect your rehabilitation programme
5. Exercises to strengthen the rotator cuff muscles and the muscles that control the shoulder blade are an essential part of management. These exercises must be gradually progressed as tendons don't like sudden changes i.e. in weights lifted or in numbers of repetitions. It is also important how the exercise is performed and your physiotherapist will give you instruction/feedback on this.
6. It is normal to experience mild pain when exercising (2-3 on a scale of 1 – 10) but this should settle shortly after exercise and should not lead to an increase in night



pain or pain the following day. It is not a case of “no pain, no gain” or “working through the pain”. (Some people with very irritable shoulder should avoid pain when exercising altogether. Your physiotherapist will advise you on this).

7. Expect tendons to take 12 weeks to heal – like bone. It is important to continue your exercises for at least one year to make stronger tendons



8. Tendons cannot heal in the presence of nicotine, so if you smoke consider cutting down or stopping altogether to aid with your recovery.
9. Our diet has a big influence on our tendon health. Fat laid down in the tendon makes them more vulnerable to injury.
10. It is important to maintain strength in other parts of our body for example in the legs and trunk. A lot of the power we generate in the shoulder for throwing, lifting etc. (greater than 50%) comes from the legs and trunk. If these areas are weak it means that our shoulders have to work harder leading to overuse (of the tendons) injuries. So on the days that you are not exercising the shoulders you should work on the strength of these areas and your general fitness.



Acknowledgements:

Karen McCreesh

Jeremy Lewis

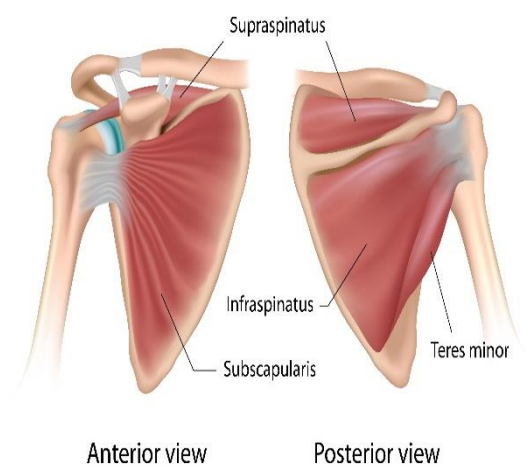




# Shoulder Clinic Booklet

## Blackrock Hall

### Physiotherapy Department





## **Shoulder Shrugs**

Standing, feet hip distance apart.  
Hands out from your sides. Lift  
your shoulders up towards your  
ears, slowly relax them down.

Repeat x 10

Progress by adding a weight in  
each hand.



### **Shoulder Retraction**

Lie on your front, forehead resting on a small 1” towel, back of neck long, arms resting long beside the body on the floor, palms facing inwards.

Gently draw the shoulder blades back and down into a V. Then reach through the fingertips & allow the arms to hover 1-2” off the mat. Keep the palms facing inwards, the head remains down & the back of the neck long.

Hold the position. Lower the hands and then allow the shoulder blades to return to the bed.



### **Weighted Pulley**

Draw down the pulley with your good arm to raise the affected hand, keeping the shoulder down.

Then lower the affected arm on its own slowly, ensuring that the shoulder stays down.

Progress by adding weights to the affected arm.





### **Serratus Anterior – Punches**

Lying on your back with your hands over your shoulders so your fingers are pointing towards the ceiling.

Reach towards the ceiling so that the back of your shoulder lifts off the plinth. Then slowly bring the back of the shoulder onto the bed, keeping the elbow straight throughout the exercise. Progress by adding weights in each hand.



**Progression:**

Kneel on your hands & knees.

Concentrate on keeping the shoulders down and away from your ears. Push down through your hands to move the breastbone away from the floor and return to the start position.



**Shoulder Retraction / Extension:**

Stand with scapula set holding  
band taut with hand in front.

Elbows straight. Pull arms back to  
your side maintaining scapular  
control.



### **External Rotation in lying or sitting**

**1.** Lying on your side, affected side uppermost, rolled up towel between your elbow & ribs, lift your forearm up & down rotating from your shoulder joint. Do not roll backwards, keep your elbow on the towel and keep it bent at a right angle.

Progress to using a weight.

**2.** Next progression to using the weight sitting with the elbow resting on a table





### **Bell Ringer**

Reach up with the affected arm stopping just before the painful point in the movement. Catch the band with the other hand and pull it down a few inches. Then catch it with the arm to be exercised (and let go with the other).

Pull the band down another few inches before allowing the band to bring the hand up (keeping the shoulder down).

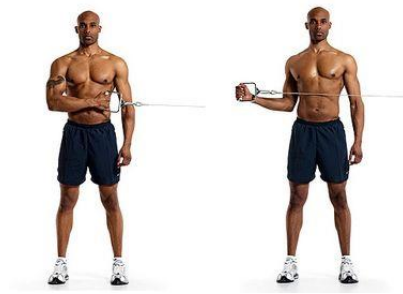


**Adductor Squeeze (Isometric Adduction)**

Hold a pillow length ways  
between your straight arm &  
body.

Concentrate on setting your  
scapula and maintaining this  
throughout the exercise. Squeeze  
the pillow with your arm.

1. Exercises to strengthen the rotator cuff muscles and the muscles that control the shoulder blade are an essential part of management. These exercises must be gradually progressed as tendons don't like sudden changes i.e. in weights lifted or in numbers of repetitions. It is also important how the exercise is performed and your physiotherapist has given you instruction/feedback on this.



2. It is normal to experience mild pain when exercising (2-3 on a scale of 1 – 10) but this should settle shortly after exercise and should not lead to an increase in night pain or pain the following day. It is not a case of “no pain, no gain” or “working through the pain”. (Some people with very irritable shoulder should avoid pain when exercising altogether. Your physiotherapist will advise you on this).

3. **Expect tendons to take 12 weeks to heal – like bone. It is important to continue your exercises for at least one year to make stronger tendons**



4. Tendons cannot heal in the presence of nicotine, so if you smoke consider cutting down or stopping altogether to aid with your recovery.
5. Our diet has a big influence on our tendon health. Fat laid down in the tendon makes them more vulnerable to injury.
6. It is important to maintain strength in other parts of our body for example in the legs and trunk. A lot of the power we generate in the shoulder for throwing, lifting etc. (greater than 50%) comes from the legs and trunk. If these areas are weak it means that our shoulders have to work harder leading to overuse (of the tendons) injuries. So on the days that you are not exercising the shoulders you should work on the strength of these areas and your general fitness.



## Appendix H

### Shoulder Pain and Disability Index (SPADI)

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## Shoulder Pain and Disability Index (SPADI)

Please place a mark on the line that best represents your experience during the last week attributable to your shoulder problem.

### Pain scale

#### How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable.

At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

### Disability scale

#### How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

THE

# Quick DASH

OUTCOME MEASURE

British English

## INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to do certain activities.

Please answer every question, based on your condition in the last week, by circling the appropriate number.

If you did not do an activity in the last week, please give your best guess which response would be most accurate.

It doesn't matter which hand or arm you use to do the activity; please answer based on your ability regardless of how you do the task.



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British English translation courtesy of: Prof Alison Hammond<sup>1</sup>,  
Dr Yeliz Prior<sup>2</sup>, Prof Sarah Tyson<sup>2</sup>

<sup>1</sup> Centre for Health Sciences Research, University of Salford;

<sup>2</sup> Centre for Long term Conditions Research, University of Manchester, UK.

## Quick DASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar	1	2	3	4	5
2. Do heavy household jobs (e.g. wash windows, clean floors)	1	2	3	4	5
3. Carry a shopping bag or briefcase	1	2	3	4	5
4. Wash your back	1	2	3	4	5
5. Use a knife to cut food	1	2	3	4	5
6. Recreational activities which require you to take some force or impact through your arm, shoulder or hand (e.g. golf, hammering, tennis etc)	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? (circle number)	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? (circle number)	1	2	3	4	5

Please rate the severity of the following symptoms in the last week (circle number)	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)	1	2	3	4	5

QuickDASH DISABILITY/SYMPTOM SCORE =  $\frac{(\text{sum of n responses}) - 1}{n} \times 25$  (where n is the number of completed responses)

A QuickDASH score may not be calculated if there is greater than 1 missing item.

### WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job / work is: \_\_\_\_\_

☐ I do not work (you may skip this section).

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Doing your work in your usual way?	1	2	3	4	5
2. Doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. Doing your work as well as you would like?	1	2	3	4	5
4. Spending your usual amount of time doing your work?	1	2	3	4	5

### SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing your musical instrument or sport or both. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you: \_\_\_\_\_

☐ I do not play a sport or an instrument. (You may skip this section).

Please circle the number that best describes your physical ability in the past week.

Did you have an difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Playing your instrument or sport in your usual way?	1	2	3	4	5
2. Playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. Playing your instrument or sport as well as you would like?	1	2	3	4	5
4. Spending your usual amount of time practicing or playing your instrument or sport?	1	2	3	4	5

Scoring the optional modules: add up the assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.

An optional module score may not be calculated if there are any missing items.



## Constant Murley Score

<b>Pain (check only one) or 15 pt linear scale Max score = 15</b>	
Severe	0
Moderate	5
Mild	10
None	15
<b>Activity Level Max score =20</b>	
Sleep Affected: (check only one)	
Yes	0
Sometimes	1
No	2
<b>Recreation/Sport Limitation: (check only one)</b>	
Severe	0
Moderate	2
No	4
<b>Daily Living Limitations: (check only one)</b>	
Severe	0
Moderate	2
No	4
<b>Arm Positioning (check only one)</b>	
Up to Waist	2
Up to Midlevel	4
Up to Neck	6
Up to Top of Head	8
Above Head	10
<b>Strength of Abduction [Pounds]</b>	
(check only one) Max score = 25 If painful score 0 points	
0	0
1-3	2
4-6	5
7-9	8
10-12	11
13-15	14
16-18	17
19-21	20
22-24	23
>24	25

<b>RANGE OF MOTION:</b>	
<b>Forward Flexion (check only one) Max score =40</b>	
31-60 degrees	2
61-90 degrees	4
91-120 degrees	6
121-150 degrees	8
151-180 degrees	10
<b>Lateral Elevation (check only one)</b>	
31-60 degrees	2
61-90 degrees	4
91-120 degrees	6
121-150 degrees	8
151-180 degrees	10
<b>External Rotation (check only one)</b>	
Hand behind Head, Elbow forward	2
Hand behind Head, Elbow back	4
Hand to top of Head, Elbow forward	6
Hand to top of Head, Elbow back	8
Full Deviation	10
<b>Internal Rotation (check only one)</b>	
Lateral Thigh	0
Buttock	2
Lumbosacral Junction	4
Wrist (L3)	8
T12 Vertebra	8
Intercapular (T7)	10

### The Constant Score Is:

Age	Male subjects			Female subjects		
	Height	Weight	Mean	Height	Weight	Mean
31-40 y	57	59	59	54	54	54
41-50 y	57	59	58	54	54	54
51-60 y	56	58	57	53	53	53
61-70 y	54	57	55	51	51	51
71-80 y	53	55	54	50	50	50
81-90 y	50	53	51	47	47	47
>91 years	45	46	45	42	42	42
91-100 y	40	38	39	37	37	37

From the British Osteoporosis Society, 1998

**Patient Global Impression of Change Scale**

Please indicate using one of the descriptions below the degree of change in your shoulder symptoms from the time you began physiotherapy treatment until now (Tick one):

Very much improved \_\_\_\_\_

Much improved \_\_\_\_\_

Slightly improved \_\_\_\_\_

No change \_\_\_\_\_

Slightly worse \_\_\_\_\_

Much worse \_\_\_\_\_

Very much worse \_\_\_\_\_

## Appendix I



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

### **Informed Consent form for a research study investigation into the management of shoulder tendinopathy**

*This consent form is provided for individuals who may be eligible to participate in research being undertaken by the PCC Physiotherapy staff investigating different physiotherapy treatments for the management of shoulder tendon pain.*

You may provide the following information either as a running paragraph or under headings as shown below.

**Principal Investigators:** Karina Teahan (KT), Deirdre Kiely (DK) & Sinead Lynch (SL).

PCC Physiotherapy Department, Blackrock Hall, Cork, Noreen Walsh (NW) Clinical Specialist Physiotherapist (South Infirmary Victoria University Hospital)

**Usual care:** Aoife Collins (AC), Linda Armstrong (LA), Elaine O'Donoghue (EO'D)

**Chief Investigator:** Dr Mark Phelan Consultant Rheumatologist South Infirmary Victoria University Hospital

**This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

**You will be given a copy of the full Informed Consent Form**

#### **PART I: Information Sheet**

##### **Introduction**

The physiotherapists listed above (KT, DK, SL, NW, AC, LA, EO'D) are undertaking research to look at 2 different types of physiotherapy treatments for clients who present with rotator cuff (shoulder muscle) pain or rotator cuff tendinopathy (a problem with the tendons around the shoulder). Rotator cuff problems are very common and thankfully very few need to be seen by an orthopaedic surgeon or need surgery. We know that physiotherapy treatment can be very effective but it is still unclear as to what type of treatment works best. Here in Blackrock Hall, we want to do research on two types of treatments and compare the results after 6 weeks of treatment.

I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, or my colleagues.

### **Purpose of the research**

Here in Blackrock Hall, we want to do research on two types of treatments and compare the results after 6 weeks of treatment. We want to do this research to help you and others who may come along with a similar injury as yours so we are providing the best possible care to our patients. We also want to share our results, anonymously, with other chartered physiotherapists. As a result, we (and you) are helping contribute to research so people with shoulder pain are receiving the treatments that work best.

### **Type of Research Intervention**

For anyone who enrolls in the study, we plan to offer you 1 of 2 types of treatment. This will be picked at random by someone who doesn't know your diagnosis and the physiotherapists doing the treatments won't be able to pick either. You will be assigned to a 'standard physiotherapy' group, where you will be offered "usual care" one-to-one physiotherapy or else you will be offered 12 sessions of group based exercises over 6 weeks. In each case you will be supervised by a physiotherapist for all sessions. We will be doing an assessment before you start (today's session, and follow up assessments after you finish the 6 weeks of treatment and again 3 & 6 months afterwards).

### **Participant selection**

You have been chosen to be invited to participate in this research as you have been referred to us with shoulder pain and on assessment you fit the criteria for either treatment option

### **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic for shoulder pain, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier and you may still avail of normal routine physiotherapy with us should you wish.

### **Procedures and Protocol**

You will be assessed by a chartered physiotherapist in order to find out more about your shoulder pain, what might have caused it, what makes it worse, what makes it better etc. The physiotherapist will also examine your shoulder, neck and arm and do some tests to look at the movement, strength and stability of the shoulder area.

Because the evidence is unclear as to which treatment type is better, we plan to treat half the group with one treatment program and the other half with a different treatment program. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin. If you are willing to participate in the study you will need to agree to being randomly assigned to one group, ie you or the physiotherapist will not be able to pick which group you go into.

Participants in one group will be offered the standard treatment that we offer at present, ie one-to-one physiotherapy. You will see the same physiotherapist at each visit, up to twice a week for 6 weeks. Treatment may consist of manual therapy, exercise, dry needling or a form of acupuncture or any other treatment your physiotherapist deems appropriate.

Participants in the other group will attend a clinic session in a group of people with shoulder pain. Exercises will be supervised by the physiotherapist and prescribed in accordance with what is recommended by research undertaken by other researchers internationally. Participants will be expected to attend twice weekly for 6 weeks.

In both groups, we will strive to use treatments that are based on research. In the case of the exercise group, the exercises that are used are based on international protocols for people with shoulder pain due to an issue with the tendons around the shoulder.

You will need to attend a number of assessments and treatment sessions:

- Your initial assessment
- Twice weekly treatment sessions for 6 weeks
- Follow up assessments after your 6 weeks of treatment and at 3 and 6 months after treatment

### **Duration**

Your treatment sessions will depend on the group you are assigned to. You can expect to be in the clinic for 30mins-1hour twice weekly. The time of the sessions will be explained to you near the start of your treatment.

### **Side Effects**

The types of treatment that we are researching are generally safe. You can expect to feel some muscle and/or joint soreness after treatment but this should settle relatively quickly.

### **Risks**

There is risk that your pain may be flared up. If this happens, your physiotherapist will reassess you and plan treatment accordingly.

### **Benefits**

By participating in this research, you will be seen twice weekly. Due to our waiting lists, this would not usually be offered to clients.

### **Reimbursements**

There is no financial compensation for participation

### **Confidentiality**

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

### **Sharing the Results**

The results of this research will be shared with you and with local and national physiotherapists. Your GP will be informed about all outcomes. No identifying features will be disclosed to anyone outside the research team

### **Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

### **Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Deirdre Kiely, Sinead Lynch or Karina Teahan on 021 4233147.

## **PART II: Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

**Print Name of Participant**\_\_\_\_\_

**Signature of Participant** \_\_\_\_\_

**Date** \_\_\_\_\_

**Day/month/year**

### **Statement by the researcher/person taking consent**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that research project proposed.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

**Print Name of Researcher/person taking the consent**\_\_\_\_\_

**Signature of Researcher /person taking the consent**\_\_\_\_\_

**Date** \_\_\_\_\_

**Day/month/year**

## **Appendix J**

### **Document 1 (CREC)**

#### **Purpose of Investigation:**

The purpose of this investigation is to evaluate & compare the clinical effectiveness of 2 different types of intervention in the management of rotator cuff tendinopathies in Blackrock Hall primary Care Physiotherapy Department. A randomised trial comparing group exercise (8 participants) versus one-to-one usual physiotherapy treatment (8 participants) will be carried out. The aim is to establish best management of shoulder tendinopathies in the community. Baseline characteristics including age, gender, past medical history, diabetes will be gathered and analysed. We hope to run 4 consecutive blocks to allow a sample size of 64 for this study. The results section of the study will clarify the number and reasons for losses to follow up.

#### **Procedures to which humans will be subjected:**

Subjects will be recruited from our musculoskeletal waiting list where they are routinely waiting for up to 4 months. Exclusion criteria are outlined in the shoulder screening document (see appendix). This, along with a structured assessment will allow us to select the suitable candidates. Outcome measures will be used as described in the Proposed Shoulder Study document (see appendix).

Group 1: 8 participants complete 1 hour classes twice weekly x 6 weeks. There is an assessment pre and post intervention, at 3 and 6 months after the classes finish. Classes are exercise based and consist of motor control, strength, mobility and cardiovascular exercises, to progressively load the rotator cuff tendon. Each patient is given an exercise manual (see appendix) with all exercises described including pictures, along with a set of

pulleys and Theraband. There is also an exercise component which outlines what causes problems with the rotator cuff, managing flare ups, the role of imaging and healthy living (see appendix).

**Group 2:** 8 participants receive one-to-one usual physiotherapy treatment. Assessment will be carried out pre treatment and at the 6 week timeline (for equivalence with Group 1), 3 months later and at 6 months later. The number of sessions and the timeframe in which they are delivered will be at the treating physiotherapist's discretion, as is current conservative practice. Treatment may include exercises, manual therapy, deep dry needling (DDN), acupuncture, advice and a home exercise programme (HEP) given on the physiotherapist's discretion.

### **Potential benefits to subjects and/or society:**



Disorders of the shoulder are extremely common, with reports of prevalence ranging from 30% of people experiencing shoulder pain at some stage in their lives, up to 50% of the population experiencing at least one episode of shoulder pain annually. Shoulder pain is often persistent and recurrent, with 54% of sufferers reporting ongoing symptoms after 3 years. (Lewis 2009)

The prevalence of Rotator Cuff (RC) disease, specifically partial & full thickness tears, has been shown to increase as a function of age starting at 40 years, and to exceed as much as 50% by the age of 60. RC disease contributes to pain & disability, and has an impact on health related QoL. Patients with shoulder pain make up a large proportion of our caseload and, due to the nature of the pathology, take a long time to improve. Our proposed treatment plan offers an intervention within a positive and supportive environment where patients understand why they are undertaking the specific exercises and have opportunities to ask questions at any time as the twice weekly classes are supervised by 2 senior physiotherapists and the one-to-one treatment is also carried out by a senior physiotherapist. In addition to this initial treatment we will follow them up at 3 and 6 months by phone or review in the clinic.

The study is very feasible in our setting as we have the gym space, minimal equipment is needed, the added benefit to this is that the patients can continue the same programme at home on discharge and hence prevent a recurrence of their problem.



## Appendix Ki



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Fax: + 353-21-490 1919

COISTE ÉITICE OM THAIGHDE CLINICIOIL  
**Clinical Research Ethics Committee**

Lancaster Hall,  
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Coláiste na hOllscoile Corcaigh, Éire  
**University College Cork, Ireland**

Our Ref: ECM 3 (kkk) 04/04/17 & ECM 3 (kk) 08/06/17

17<sup>th</sup> May 2017

Dr Mark Phelan  
Consultant Rheumatologist  
South Infirmary Victoria University Hospital  
Infirmary Road  
Cork

**Re: A randomised trial study comparing group therapeutic exercise classes with traditional physiotherapy treatment of rotator cuff tendinopathy in the Primary Care setting.**

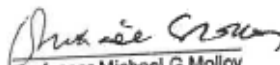
Dear Dr Phelan

The Chairman approved the following:

- Cover Letter dated 12<sup>th</sup> May 2017
- Revised informed consent form
- Evidence of insurance.

Full approval is now granted to begin the above study.

Yours sincerely

  
Professor Michael G Molloy  
Chairman  
Clinical Research Ethics Committee  
of the Cork Teaching Hospitals

*The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice*

Ollscoil na hÉireann, Corcaigh - National University of Ireland, Cork.



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Coláiste na hOllscoile Corcaigh, Éire  
University College Cork, Ireland

COISTE EITICE UM THAIGHIDE CLINIC  
Clinical Research Ethics Committee

Lancaster Hall,  
6 Little Hanover Street,  
Cork,  
Ireland.

Our Ref: ECM 3 (kkk) 04/04/17

7<sup>th</sup> April 2017

Dr Mark Phelan  
Consultant Rheumatologist  
South Infirmary Victoria University Hospital  
Infirmary Road  
Cork

Re: A randomised trial study comparing group therapeutic exercise classes with traditional physiotherapy treatment of rotator cuff tendinopathy in the Primary Care setting.

Dear Dr Phelan

Approval will be granted to carry out the above study at:

- Physiotherapy Department Blackrock Hill Primary Care Centre

subject to receipt and approval of the following:

- Revised informed consent form: see attached
- Evidence of insurance.

The following documents have been approved:

- Application form signed 20 February 2017 (received 14 March 2017)
- GP letter
- Shoulder screening form
- Rotator cuff impingement syndrome test
- Outcome measures questionnaires
- Exercise manual
- Educational component
- CV for chief investigator.

We note that the following co-investigators will be involved in the above study:

- Karina Teahan, Deirdre, Kiely, Sinead Lynch, Aoife Collins, Senior Msk Physiotherapists, Noreen Walsh, Clinical Specialist in Physiotherapy, Linda Armstrong and Elaine O'Donoghue, Physiotherapists.

Yours sincerely

Professor Michael G Molloy  
Chairman  
Clinical Research Ethics Committee  
of the Cork Teaching Hospitals

*The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice*

## Appendix Kii



South Infirmary - Victoria University Hospital Ltd.  
Old Blackrock Road, Cork. T12 X23H  
Tel: 021- 4926169  
E-mail: [ceo@sivuh.ie](mailto:ceo@sivuh.ie)

**South Infirmary - Victoria University Hospital**  
Ollscoil Ospidéal Otharlann an Deiscirt-Victoria  
A Teaching Hospital of University College, Cork.

HD/NB

29<sup>th</sup> May 2017

Dr. Mark Phelan  
Consultant Rheumatologist  
SIVUH

Re: "A randomised trial study comparing group therapeutic exercise classes with traditional physiotherapy treatment of rotator cuff tendinopathy in the Primary Care setting"

Dear Dr. Phelan,

I refer to the above research proposal received in the CEO's office on the 25<sup>th</sup> May 2017 requesting permission to carry out the above study at this hospital.

I confirm that the study, which was approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals, was approved by our Board of Directors at their meeting on the 29<sup>th</sup> May 2017.

Yours sincerely,

Ms Helen Donovan  
Chief Executive Officer

C.C. Ms Margaret Lynch, Quality & Risk Manager, SIVUH

## Appendix L

### Baseline characteristics and outcome measures SPADI

Subject No	SP0	SP0 (P)	SP0 (D)	SP6	SP6 (P)	SP6 (D)	SP0- SP6	SP6diff (P)	SP6diff (D)	% change at 6/52	SP12	SP12 (P)	SP12 (D)	SP0- SP12	SP12diff (P)	SP12diff (D)	% Change at 12/52	SP24	SP24 (P)	SP24 (D)	SP0- SP24	SP24diff (P)	SP24diff (D)	% change at 24/52
1	40	34	43.75	0	0	0	40	34	43.75	100.00	0	0	0	40	34	43.75	100.00	4.6	8	2.5	35.4	26	41.25	88.50
2	1.5	2	1.25	14.62	12	16.25	-13.12	-10	-15	-874.67	6.15	8	5	-4.65	-6	-3.75	-310.00	3	0	5	-1.5	2	-3.75	-100.00
3	35	52	25	10	12	8.75	25	40	16.25	71.43	29.23	30	28.75	5.77	22	-3.75	16.49	14.6	16	13.75	20.4	36	11.25	58.29
4	48.4	42	52.5	43.8	52	38.75	4.6	-10	13.75	9.50	78.46	82	76.25	-30.06	-40	-23.75	-62.11	23.07	26	21.25	25.33	16	31.25	52.33
5	66	58	71.25	73.07	72	73.75	-7.07	-14	-2.5	-10.71	50	68	38.75	16	-10	32.5	24.24	38.46	64	22.5	27.54	-6	48.75	41.73
6	75.3	78	73.75	80	82	78.75	-4.7	-4	-5	-6.24	76.15	82	72.5	-0.85	-4	1.25	-1.13	61.5	68	57.5	13.8	10	16.25	18.33
7	40	62	26.25	21.54	68	35	18.46	-6	-8.75	46.15	42.3	60	31.25	-2.3	2	-5	-5.75	23.85	36	16.25	16.15	26	10	40.38
8	82.3	82	82.5	73.85	84	67.5	8.45	-2	15	10.27	63.08	62	63.75	19.22	20	18.75	23.35	22.3	24	21.25	60	58	61.25	72.90
9	61.54	64	60	13.84	20	10	47.7	44	50	77.51	26.15	36	20	35.39	28	40	57.51	26.15	36	20	35.39	28	40	57.51
10	51.5	72	38.75	10	18	5	41.5	54	33.75	80.58	10	18	5	41.5	54	33.75	80.58	0	0	0	51.5	72	38.75	100.00
11	38.46	58	26.25	26.9	36	21.25	11.56	22	5	30.06	15.38	24	10	23.08	34	16.25	60.01	13.85	22	8.75	24.61	36	17.5	63.99
12	95.38	100	92.5	42.31	40	43.75	53.07	60	48.75	55.64	33.08	38	30	62.3	62	62.5	65.32	67.69	82	58.75	27.69	18	33.75	29.03
13	81.54	94	73.75	26.92	32	23.75	54.62	62	50	66.99	26.15	22	28.75	55.39	72	45	67.93	30	42	22.5	51.54	52	51.25	63.21
14	29.23	34	26.25	30.7	42	23.75	-1.47	-8	2.5	-5.03	6.15	10	3.75	23.08	24	22.5	78.96	6.92	14	2.5	22.31	20	23.75	76.33
15	17.69	46	0	17.69	46	0	0	0	0	0.00	17.69	46	0	0	0	0	0.00	17.69	46	0	0	0	0	0.00
16	64.61	76	57.5	39.2	50	32.5	25.41	26	25	39.33	40	46	36.25	24.61	30	21.25	38.09	49.23	76	32.5	15.38	0	25	23.80
17	65.38	78	57.5	48.46	60	47.5	16.92	18	10	25.88	52.31	54	45	13.07	24	12.5	19.99	44.62	66	31.25	20.76	12	26.25	31.75
18	30	30	30	43.07	48	40	-13.07	-18	-10	-43.57	20	20	20	10	10	10	33.33	12.3	20	7.5	17.7	10	22.5	59.00
19	65.38	86	52.5	50.77	68	40	14.61	18	12.5	22.35	34.6	46	27.5	30.78	40	25	47.08	43.18	58	32.5	22.2	28	20	33.96
20	80	88	75	80	88	75	0	0	0	0.00	80	88	75	0	0	0	0.00	80	88	75	0	0	0	0.00
21	19.23	36	8.75	59.23	56	61.25	-40	-20	-52.5	-208.01	21.5	30	16.25	-2.27	6	-7.5	-11.80	21.53	24	20	-2.3	12	-11.25	-11.96
22	80.77	74	85	80.77	74	85	0	0	0	0.00	80.77	74	85	0	0	0	0.00	80.77	74	85	0	0	0	0.00
23	61.5	64	60	61.5	64	60	0	0	0	0.00	61.5	64	60	0	0	0	0.00	61.5	64	60	0	0	0	0.00
24	46	52	42.5	51.54	60	46.25	-5.54	-8	-3.75	-12.04	16.92	20	15	29.08	32	27.5	63.22	7.69	8	7.5	38.31	44	35	83.28
25	61.5	60	62.5	47.69	52	45	13.81	8	17.5	22.46	6.92	10	5	54.58	50	57.5	88.75	13.85	22	8.75	47.65	38	53.75	77.48
26	81.5	94	73.75	80	80	80	1.5	14	-6.25	1.84	83.08	86	81.25	-1.58	8	-7.5	-1.94	77.7	84	73.75	3.8	10	0	4.66
27	70	90	57.5	38.46	50	31.25	31.54	40	26.25	45.06	26.15	34	21.25	43.85	56	36.25	62.64	24.61	40	15	45.39	50	42.5	64.84
28	54.6	64	48.75	14.61	22	10	39.99	42	38.75	73.24	11.54	16	8.75	43.06	48	40	78.86	13.08	20	8.75	41.52	44	40	76.04
29	39	54	30	6.15	4	7.5	32.85	50	22.5	84.23	6.92	10	5	32.08	44	25	82.26	1.5	2	1.25	37.5	52	28.75	96.15

Subject	SP0-						SP6diff				% change at		SP12		SP12		SP0-		SP12diff		SP12diff		% Change at		SP24		SP24		SP0-		SP24diff		SP24diff		% change at	
No	SP0	SP0 (P)	SP0 (D)	SP6	SP6 (P)	SP6(D)	SP6	(P)	(D)	6/52	SP12	(P)	(D)	SP12	(P)	(D)	SP12	(P)	(D)	SP12diff	(P)	(D)	12/52)	SP24	(P)	(D)	SP24	(P)	(D)	SP24	(P)	(D)	24/52)			
30	74.6	80	71.25	55.38	66	48.75	19.22	14	22.5	25.76	30	38	25	44.6	42	46.25	59.79	53.85	86	33.75	20.75	-6	37.5	27.82												
31	82.3	82	82.5	7.69	8	7.5	74.61	74	75	90.66	10	10	10	72.3	72	72.5	87.85	0.77	0	1.25	81.53	82	81.25	99.06												
32	21.5	42	8.75	8.46	14	5	13.04	28	3.75	60.65	3.84	8	1.25	17.66	34	7.5	82.14	5.38	10	2.5	16.12	32	6.25	74.98												
33	76	88	68.75	76	88	68.75	0	0	0	0.00	76	88	68.75	0	0	0	0.00	76	88	68.75	0	0	0	0.00												
34	58	78	46.25	67.69	82	58.75	-9.69	-4	-12.5	-16.71	63.08	72	57.5	-5.08	6	-11.25	-8.76	59.23	52	63.75	-1.23	26	-17.5	-2.12												
35	86.9	100	78.75	86.9	100	78.75	0	0	0	0.00	86.9	100	78.75	0	0	0	0.00	86.9	100	78.75	0	0	0	0.00												
36	38.46	54	28.75	21.54	30	16.25	16.92	24	12.5	43.99	21.54	30	16.25	16.92	24	12.5	43.99	21.54	30	16.25	16.92	24	12.5	43.99												
37	56.15	68	48.75	56.15	68	48.75	0	0	0	0.00	56.15	68	48.75	0	0	0	0.00	56.15	68	48.75	0	0	0	0.00												
38	70.77	80	65	41.5	56	32.5	29.27	24	32.5	41.36	15.4	30	6.25	55.37	50	58.75	78.24	12.31	16	10	58.46	64	55	82.61												
39	49.23	62	41.25	47.5	54	42.86	1.73	8	-1.61	3.51	34.6	52	23.75	14.63	10	17.5	29.72	46.92	48	46.25	2.31	14	-5	4.69												
40	65.38	66	65	80.77	82	80	-15.39	-16	-15	-23.54	23.08	18	26.25	42.3	48	38.75	64.70	61	58	62.5	4.38	8	2.5	6.70												
41	33.85	30	36.25	6.15	4	7.5	27.7	26	28.75	81.83	8.5	8	8.75	25.35	22	27.5	74.89	0	0	0	33.85	30	36.25	100.00												
42	57.69	48	63.75	26.9	30	25	30.79	18	38.75	53.37	60.77	64	58.75	-3.08	-16	5	-5.34	20	20	20	37.69	28	43.75	65.33												
43	63.85	72	58.75	28.46	40	21.25	35.39	32	37.5	55.43	4.6	4	5	59.25	68	53.75	92.80	6.9	10	5	56.95	62	53.75	89.19												
44	22.31	28	18.75	14.6	20	11.25	7.71	8	7.5	34.56	10	16	6.25	12.31	12	12.5	55.18	16.15	22	12.5	6.16	6	6.25	27.61												
45	66.15	76	60	25.3	34	20	40.85	42	40	61.75	10.7	20	5	55.45	56	55	83.82	23.84	40	13.75	42.31	36	46.25	63.96												
46	31.54	46	22.5	26.15	16	32.5	5.39	30	-10	17.09	12.3	18	8.75	19.24	28	13.75	61.00	3.07	4	2.5	28.47	42	20	90.27												
47	76.9	76	77.5	66.1	72	62.5	10.8	4	15	14.04	49.23	70	36.25	27.67	6	41.25	35.98	68.46	84	58.75	8.44	-8	18.75	10.98												
48	35.38	64	17.5	8.46	16	3.75	26.92	48	13.75	76.09	5	10	2.5	30.38	54	15	85.87	0	0	0	35.38	64	17.5	100.00												
49	77.69	60	88.75	38.46	8	56.25	39.23	52	32.5	50.50	20	8	28.57	57.69	52	60.18	74.26	16.92	0	27.5	60.77	60	61.25	78.22												
50	27.69	36	22.5	18.5	24	15	9.19	12	7.5	33.19	11.53	18	7.5	16.16	18	15	58.36	8.46	18	2.5	19.23	18	20	69.45												
51	52.3	54	51.25	26.9	20	31.25	25.4	34	20	48.57	23.07	24	22.5	29.23	30	28.75	55.89	22.31	24	21.25	29.99	30	30	57.34												
52	35.4	44	30	16.2	16	16.25	19.2	28	13.75	54.24	9.23	14	6.25	26.17	30	23.75	73.93	4.62	6	3.75	30.78	38	26.25	86.95												
53	44.6	64	32.5	53	56	51.25	-8.4	8	-18.75	-18.83	48.46	52	46.25	-3.86	12	-13.75	-8.65	32.3	36	30	12.3	28	2.5	27.58												
54	61.5	92	42.5	34.6	52	23.75	26.9	40	18.75	43.74	33.84	52	22.5	27.66	40	20	44.98	25.38	52	8.75	36.12	40	33.75	58.73												
55	39	50	32.5	9.2	10	8.75	29.8	40	23.75	76.41	22.3	32	16.25	16.7	18	16.25	42.82	8.46	14	5	30.54	36	27.5	78.31												
56	31.5	44	23.75	37.7	54	27.5	-6.2	-10	-3.75	-19.68	7.69	6	10	23.81	38	13.75	75.59	7.69	12	5	23.81	32	18.75	75.59												
57	100	100	100	100	100	100	0	0	0	0.00	100	100	100	0	0	0	0.00	100	100	100	0	0	0	0.00												
58	41.5	62.5	36.25	32.3	42	26.25	9.2	20.5	10	22.17	57.5	70	51.25	-16	-7.5	-15	-38.55	0	0	0	41.5	62.5	36.25	100.00												
59	86.15	90	83.75	64.6	88	50	21.55	2	33.75	25.01	83.85	78	87.5	2.3	12	-3.75	2.67	55.38	72	45	30.77	18	38.75	35.72												
60	60.7	78	50	50.76	52	50	9.94	26	0	16.38	20.76	40	8.75	39.94	38	41.25	65.80	11.5	10	12.5	49.2	68	37.5	81.05												

Subject No	SP0	SP0 (P)	SP0 (D)	SP6	SP6 (P)	SP6(D)	SP0-SP6	SP6diff (P)	SP6diff (D)	% change at 6/52	SP12	SP12 (P)	SP12 (D)	SP0-SP12	SP12diff (P)	SP12diff (D)	% Change at 12/52	SP24	SP24 (P)	SP24 (D)	SP0-SP24	SP24diff (P)	SP24diff (D)	% change at 24/52
61	16	32	6.25	23.85	46	10	-7.85	-14	-3.75	-49.06	23.85	46	10	-7.85	-14	-3.75	-49.06	25.38	58	5	-9.38	-26	1.25	-58.63
62	18.46	24	15	10.76	14	8.75	7.7	10	6.25	41.71	7.69	14	3.75	10.77	10	11.25	58.34	2.3	2	2.5	16.16	22	12.5	87.54
63	24	28	22.5	19.2	22	17.5	4.8	6	5	20.00	24.62	32	20	-0.62	-4	2.5	-2.58	32.31	32	32.5	-8.31	-4	-10	-34.63
64	38.46	60	25	36.92	64	20	1.54	-4	5	4.00	32	52	20	6.46	8	5	16.80	34.62	46	27.5	3.84	14	-2.5	9.98
65	50	76	33.75	33.07	46	25	16.93	30	8.75	33.86	33.07	48	23.75	16.93	28	10	33.86	9.2	12	7.5	40.8	64	26.25	81.60
66	44.61	70	28.75	44.61	70	28.75	0	0	0	0.00	44.61	70	28.75	0	0	0	0.00	44.61	70	28.75	0	0	0	0.00
67	41.53	28	50	45.38	34	52.5	-3.85	-6	-2.5	-9.27	30.76	44	22.5	10.77	-16	27.5	25.93	70	82	62.5	-28.47	-54	-12.5	-68.55
68	56.92	66	51.25	34.62	38	32.5	22.3	28	18.75	39.18	46.15	42	48.75	10.77	24	2.5	18.92	30	40	11.25	26.92	26	40	47.29
69	24.6	20	27.5	23.08	20	25	1.52	0	2.5	6.18	16.15	12	18.75	8.45	8	8.75	34.35	10.76	6	8	13.84	14	19.5	56.26

# Baseline characteristics and outcome measures QuickDASH

Subject No	%change at			QD0- QD12			% change at			% change at
	QD0	QD6	QD0-QD6	6/52	QD12	QD0-QD12	12/52	QD24	QD0-QD24	
1	47.7	11.36	36.34	76.18	0	47.7	100.00	9.09	38.61	80.94
2	31.8	18.18	13.62	42.83	6.81	24.99	78.58	11.36	20.44	64.28
3	25	10	15	60.00	35	-10	-40.00	11.36	13.64	54.56
4	47.7	36.3	11.4	23.90	47.72	-0.02	-0.04	27.27	20.43	42.83
5	50	40.91	9.09	18.18	27.27	22.73	45.46	22.7	27.3	54.60
6	59	59.09	-0.09	-0.15	45	14	23.73	56.8	2.2	3.73
7	36.36	36.36	0	0.00	38.63	-2.27	-6.24	18.18	18.18	50.00
8	45.4	54.54	-9.14	-20.13	61	-15.6	-34.36	34.09	11.31	24.91
9	20.4	0	20.4	100.00	6.81	13.59	66.62	6.81	13.59	66.62
10	68.18	27.27	40.91	60.00	27.27	40.91	60.00	11.36	56.82	83.34
11	47.7	27.2	20.5	42.98	20.45	27.25	57.13	25	22.7	47.59
12	95.45	29.54	65.91	69.05	25	70.45	73.81	84.1	11.35	11.89
13	45.45	18.18	27.27	60.00	18.18	27.27	60.00	13.63	31.82	70.01
14	29.54	15.9	13.64	46.17	11.36	18.18	61.54	12.5	17.04	57.68
15	2.27	2.27	0	0.00	2.27	0	0.00	2.27	0	0.00
16	52.27	18.18	34.09	65.22	31.8	20.47	39.16	45.45	6.82	13.05
17	79.54	45.45	34.09	42.86	43.18	36.36	45.71	57.27	22.27	28.00
18	45.45	40	5.45	11.99	20.45	25	55.01	18.18	27.27	60.00
19	65.9	45.45	20.45	31.03	50	15.9	24.13	42.3	23.6	35.81
20	70.45	70.45	0	0.00	70.45	0	0.00	70.45	0	0.00
21	11.36	25	-13.64	-120.07	9.09	2.27	19.98	6.81	4.55	40.05
22	75	75	0	0.00	75	0	0.00	75	0	0.00
23	72.7	72.7	0	0.00	72.7	0	0.00	72.7	0	0.00
24	59	59.09	-0.09	-0.15	43.18	15.82	26.81	20.45	38.55	65.34
25	61.3	40.9	20.4	33.28	6.82	54.48	88.87	18.18	43.12	70.34
26	70.4	59.09	11.31	16.07	61.36	9.04	12.84	65.9	4.5	6.39
27	36.4	25	11.4	31.32	11.36	25.04	68.79	11.36	25.04	68.79
28	31.8	20.45	11.35	35.69	31.82	-0.02	-0.06	22.73	9.07	28.52
29	25	4.54	20.46	81.84	4.54	20.46	81.84	2.27	22.73	90.92
30	79.5	72.72	6.78	8.53	45.45	34.05	42.83	34.09	45.41	57.12
31	54.5	6.81	47.69	87.50	11.36	43.14	79.16	4.54	49.96	91.67
32	15.9	9.09	6.81	42.83	2.27	13.63	85.72	4.55	11.35	71.38
33	61.36	61.36	0	0.00	61.36	0	0.00	61.36	0	0.00
34	56.8	63.63	-6.83	-12.02	43.18	13.62	23.98	47.73	9.07	15.97
35	85	85	0	0.00	85	0	0.00	85	0	0.00
36	31.81	22.73	9.08	28.54	22.73	9.08	28.54	22.73	9.08	28.54



Subject	%change at			QD0-		%change at		% change at		
No	QD0	QD6	QD0-QD6	6/52	QD12	QD12	12/52	QD24	QD0-QD24	24/52
37	61.3	61.3	0	0.00	61.3	0	0.00	61.3	0	0.00
38	43.18	35	8.18	18.94	13.6	29.58	68.50	11.36	31.82	73.69
39	43.18	36.36	6.82	15.79	34.1	9.08	21.03	40	3.18	7.36
40	40.9	40.9	0	0.00	25	15.9	38.88	40.9	0	0.00
41	25	6.8	18.2	72.80	2.3	22.7	90.80	4.54	20.46	81.84
42	43.18	50	-6.82	-15.79	61	-17.82	-41.27	18.1	25.08	58.08
43	36.3	38.63	-2.33	-6.42	6.8	29.5	81.27	6.8	29.5	81.27
44	11.36	20.45	-9.09	-80.02	18	-6.64	-58.45	20.45	-9.09	-80.02
45	43.18	40.9	2.28	5.28	13.6	29.58	68.50	6.81	36.37	84.23
46	47.73	25	22.73	47.62	11.36	36.37	76.20	18.18	29.55	61.91
47	55	47.72	7.28	13.24	27.27	27.73	50.42	54.54	0.46	0.84
48	18.18	2.27	15.91	87.51	2.5	15.68	86.25	0	18.18	100.00
49	97.72	63.6	34.12	34.92	40	57.72	59.07	38.6	59.12	60.50
50	32.5	29.5	3	9.23	0	32.5	100.00	0	32.5	100.00
51	52.5	27.3	25.2	48.00	15.9	36.6	69.71	13.64	38.86	74.02
52	43	9.09	33.91	78.86	4.54	38.46	89.44	4.54	38.46	89.44
53	38.6	17.5	21.1	54.66	34.09	4.51	11.68	29.54	9.06	23.47
54	84.1	20.5	63.6	75.62	34.09	50.01	59.46	25	59.1	70.27
55	63.6	4.5	59.1	92.92	25	38.6	60.69	6.81	56.79	89.29
56	38.6	29.5	9.1	23.58	0	38.6	100.00	2.27	36.33	94.12
57	91	91	0	0.00	91	0	0.00	91	0	0.00
58	15.9	29.5	-13.6	-85.53	27.2	-11.3	-71.07	0	15.9	100.00
59	43	40.9	2.1	4.88	47.73	-4.73	-11.00	52.27	-9.27	-21.56
60	63.6	36.3	27.3	42.92	22.73	40.87	64.26	45.4	18.2	28.62
61	11.36	15.91	-4.55	-40.05	15.91	-4.55	-40.05	34.09	-22.73	-200.09
62	13.6	15.9	-2.3	-16.91	9.09	4.51	33.16	2.27	11.33	83.31
63	36.36	18.18	18.18	50.00	20.45	15.91	43.76	36.36	0	0.00
64	36.3	34.09	2.21	6.09	36.36	-0.06	-0.17	38.64	-2.34	-6.45
65	20.45	18.18	2.27	11.10	10	10.45	51.10	9.09	11.36	55.55
66	50	50	0	0.00	50	0	0.00	50	0	0.00
67	34.09	45.45	-11.36	-33.32	52.27	-18.18	-53.33	68.18	-34.09	-100.00
68	61.3	50	11.3	18.43	50	11.3	18.43	52.3	9	14.68
69	29.5	18.18	11.32	38.37	13.63	15.87	53.80	13.63	15.87	53.80



# Baseline characteristics and outcome measures CM

Subject No	CM0	CM6	CM6- CM0	% change at 6/52	CM12	CM12- CM0	% change at 12/52	CM24	CM24- CM0	% change at 24/52
1	38	81	43	113.16	88	50	131.58	76	38	100.00
2	65	72	7	10.77	70	5	7.69	73	8	12.31
3	48	57	9	18.75	64	16	33.33	75	27	56.25
4	48	62	14	29.17	65	17	35.42	65	17	35.42
5	26	28	2	7.69	40	14	53.85	28	2	7.69
6	38	50	12	31.58	64	26	68.42	72	34	89.47
7	78	73	-5	-6.41	78	0	0.00	77	-1	-1.28
8	34	52	18	52.94	61	27	79.41	72	38	111.76
9	48	87	39	81.25	84	36	75.00	84	36	75.00
10	61	71	10	16.39	71	10	16.39	100	39	63.93
11	59	67	8	13.56	75	16	27.12	88	29	49.15
12	32	73	41	128.13	75	43	134.38	57	25	78.13
13	65	76	11	16.92	65	0	0.00	75	10	15.38
14	62	69	7	11.29	74	12	19.35	77	15	24.19
15	74	74	0	0.00	74	0	0.00	74	0	0.00
16	57	68	11	19.30	76	19	33.33	55	-2	-3.51
17	63	60	-3	-4.76	74	11	17.46	56	-7	-11.11
18	40	46	6	15.00	56	16	40.00	77	37	92.50
19	48	63	15	31.25	74	26	54.17	74	26	54.17
20	35	35	0	0.00	35	0	0.00	35	0	0.00
21	55	61	6	10.91	63	8	14.55	63	8	14.55
22	28	28	0	0.00	28	0	0.00	28	0	0.00
23	45	45	0	0.00	45	0	0.00	45	0	0.00
24	43	44	1	2.33	59	16	37.21	78	35	81.40
25	47	58	11	23.40	79	32	68.09	84	37	78.72
26	32	44	12	37.50	41	9	28.13	36	4	12.50
27	26	29	3	11.54	44	18	69.23	51	25	96.15
28	62	70	8	12.90	79	17	27.42	87	25	40.32
29	56	98	42	75.00	96	40	71.43	98	42	75.00
30	26	52	26	100.00	55	29	111.54	73	47	180.77
31	48	84	36	75.00	77	29	60.42	84	36	75.00
32	71	95	24	33.80	88	17	23.94	96	25	35.21
33	57	57	0	0.00	57	0	0.00	57	0	0.00
34	55	70	15	27.27	41	-14	-25.45	71	16	29.09

Subject No	CM0	CM6	CM6-CM0	% change at 6/52	CM12	CM12-CM0	% change at 12/52	CM24	CM24-CM0	% change at 24/52
35	57	57	0	0.00	57	0	0.00	57	0	0.00
36	58	63	5	8.62	57	-1	-1.72	57	-1	-1.72
37	38	38	0		38	0	0.00	38	0	0.00
38	62	81	19	30.65	82	20	32.26	84	22	35.48
39	50	48	-2	-4.00	63	13	26.00	64	14	28.00
40	39	46	7	17.95	42	3	7.69	58	19	48.72
41	61	82	21	34.43	81	20	32.79	81	20	32.79
42	34	62	28	82.35	65	31	91.18	65	31	91.18
43	47	62	15	31.91	81	34	72.34	81	34	72.34
44	88	93	5	5.68	93	5	5.68	79	-9	-10.23
45	64	67	3	4.69	75	11	17.19	74	10	15.63
46	57	60	3	5.26	77	20	35.09	81	24	42.11
47	56	38	-18	-32.14	45	-11	-19.64	38	-18	-32.14
48	51	70	19	37.25	68	17	33.33	76	25	49.02
49	30	63	33	110.00	84	54	180.00	82	52	173.33
50	46	78	32	69.57	81	35	76.09	81	35	76.09
51	65	74	9	13.85	79	14	21.54	83	18	27.69
52	46	78	32	69.57	83	37	80.43	78	32	69.57
53	30	68	38	126.67	62	32	106.67	75	45	150.00
54	40	81	41	102.50	72	32	80.00	90	50	125.00
55	52	74	22	42.31	64	12	23.08	72	20	38.46
56	68	79	11	16.18	80	12	17.65	91	23	33.82
57	28	28	0	0.00	28	0	0.00	28	0	0.00
58	65	80	15	23.08	63	-2	-3.08	95	30	46.15
59	63	65	2	3.17	67	4	6.35	76	13	20.63
60	39	62	23	58.97	66	27	69.23	68	29	74.36
61	70	73	3	4.29	73	3	4.29	63	-7	-10.00
62	75	82	7	9.33	86	11	14.67	92	17	22.67
63	65	77	12	18.46	75	10	15.38	74	9	13.85
64	58	63	5	8.62	70	12	20.69	63	5	8.62
65	58	72	14	24.14	68	10	17.24	76	18	31.03
66	66	66	0	0.00	66	0	0.00	66	0	0.00
67	48	46	-2	-4.17	56	8	16.67	44	-4	-8.33
68	57	67	10	17.54	60	3	5.26	71	14	24.56
69	71	84	13	18.31	85	14	19.72	84	13	18.31

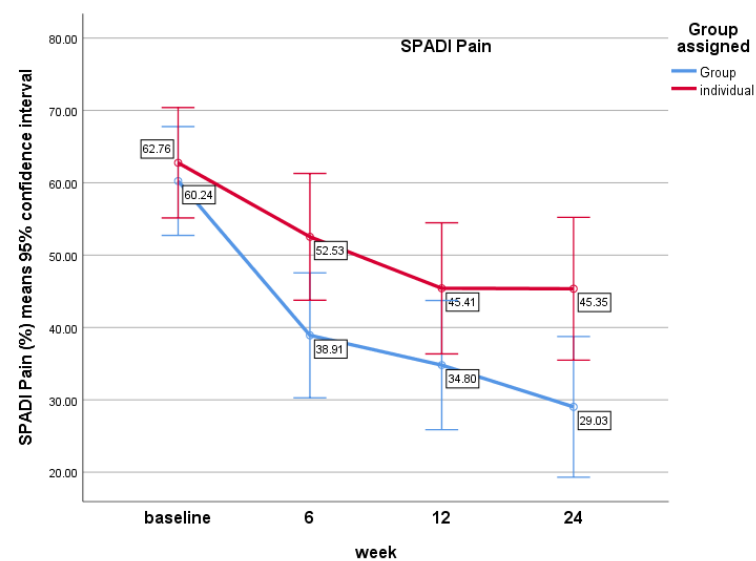
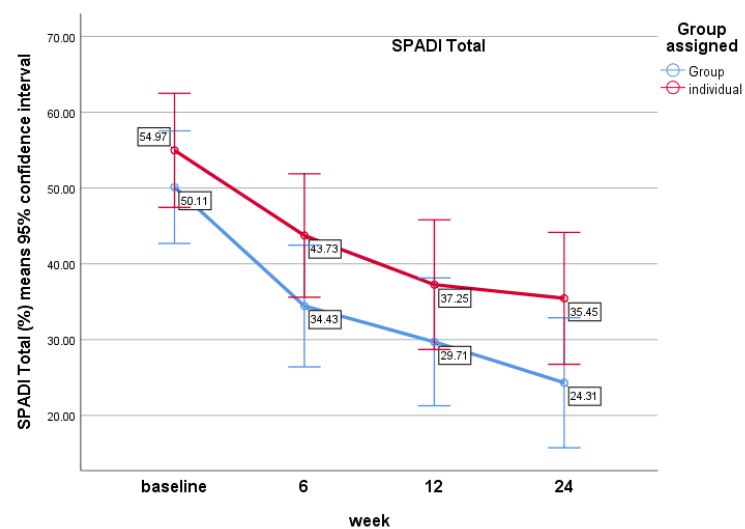
Baseline characteristics and outcome measures PGIC

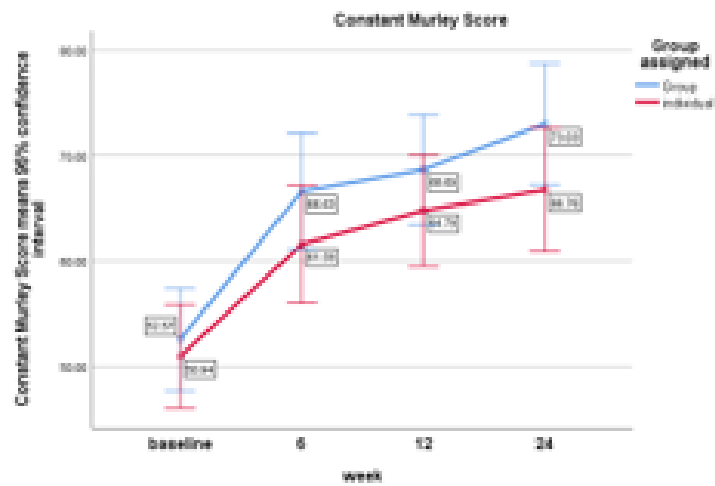
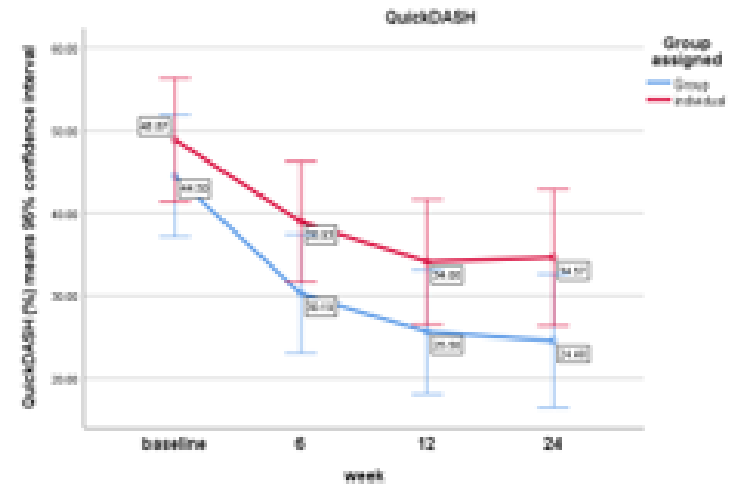
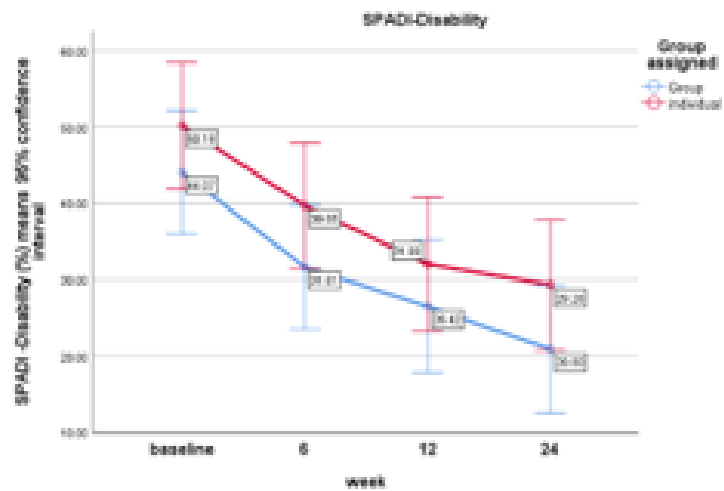
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2		5	1	6	1	5	1
3		5	1	6	1	5	1
4		5	1	5	1	5	1
5		6	1	6	1	4	0
6		4	0	5	1	5	1
7		3	0	4	0	4	0
8		5	1	5	1	5	1
9		6	1	6	1		
10		6	1			6	1
11		5	1	5	1	5	1
12		5	1	6	1	1	0
13		6	1	6	1	6	1
14		4	0	4	0	5	1
15							
16				5	1	4	0
17		4	0	5	1	4	0
18		4	0	4	0	5	1
19		5	1	5	1	5	1
20							
21		5	1	5	1	4	0
22							
23							
24		4	0	5	1	6	1
25		2	0	6	1	5	1
26		4	0	5	1	4	0
27		4	0	4	0	3	0
28		6	1	6	1	6	1
29		6	1	6	1	6	1
30		4	0	5	1	5	1
31		6	1	6	1	6	1
32		6	1	5	1	5	1
33							
34		5	1	5	1	6	1
35							
36		5	1				

Subject							
No	PGIC0	PGIC6	status	PGIC12	status	PGIC24	status
37							
38		5	1	6	1	5	1
39		5	1	6	1	6	1
40		4	0	5	1	5	1
41		6	1	6	1	6	1
42		6	1	5	1	6	1
43		5	1	6	1	6	1
44		4	0	4	0	4	0
45		5	1	6	1	5	1
46		6	1	6	1	6	1
47		4	0	5	1	4	0
48		4	0	6	1	5	1
49		5	1	6	1	6	1
50		6	1	5	1	6	1
51		5	1	5	1	5	1
52		6	1	6	1	6	1
53		5	1	5	1	6	1
54		5	1	5	1	5	1
55		6	1	5	1	6	1
56		5	1	6	1	6	1
57							
58		6	1	2	0	6	1
59		5	1	5	1	5	1
60		5	1	6	1	6	1
61		4	0			2	0
62		5	1	6	1	6	1
63		5	1	6	1	5	1
64		4	0	4	0	4	0
65		5	1	5	1	6	1
66							
67		2	0	3	0	3	0
68		5	1	5	1	4	0
69		5	1	6	1	5	1

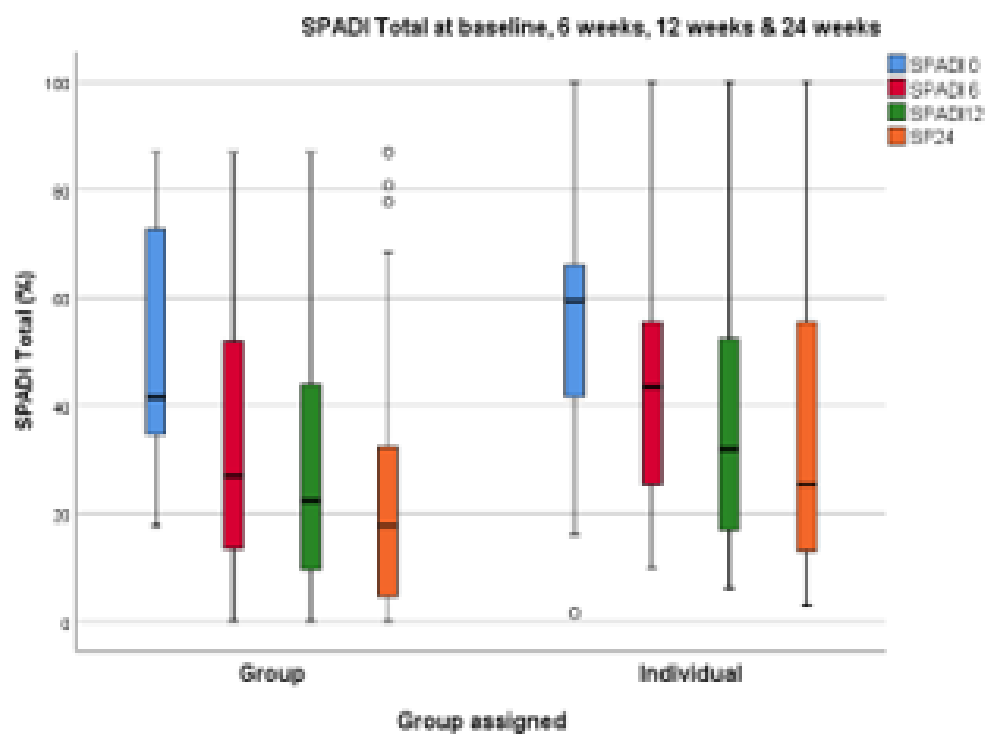
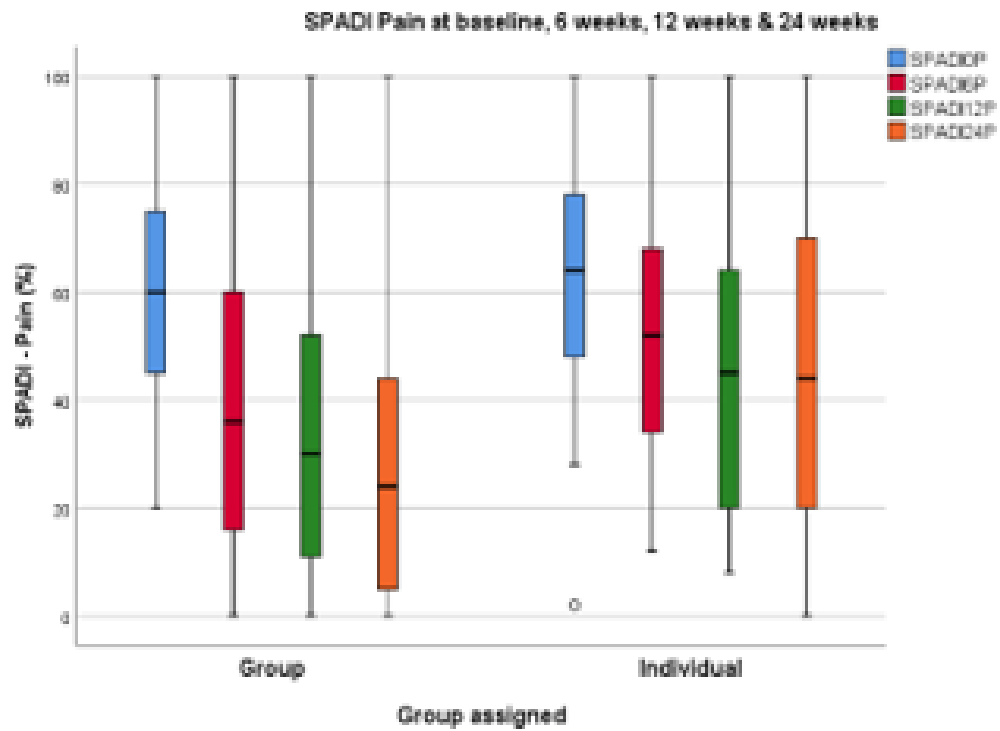
## Appendix M

### Line Graphs of continuous data outcome measures at baseline and follow-ups

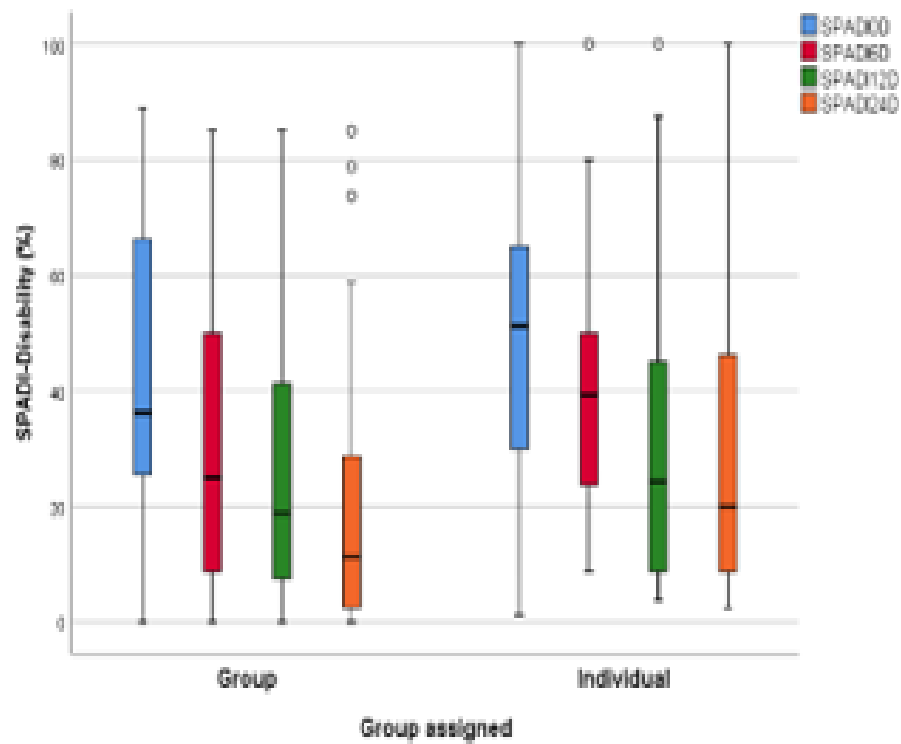




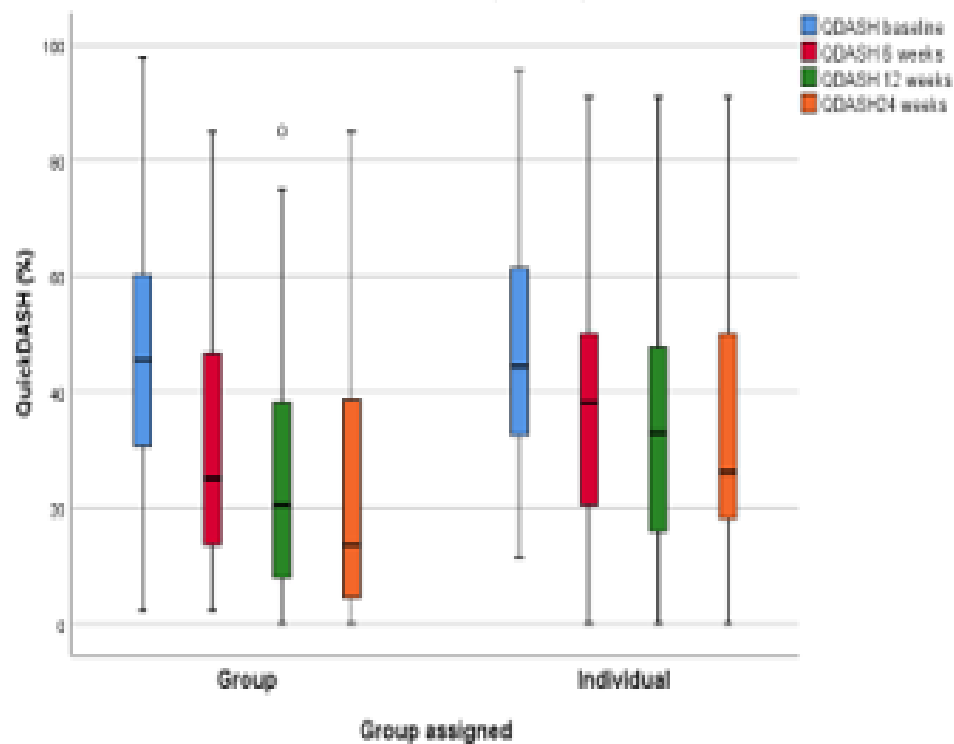
<sup>1</sup> **Bar Graphs of continuous data outcome measures at baseline and follow-ups**



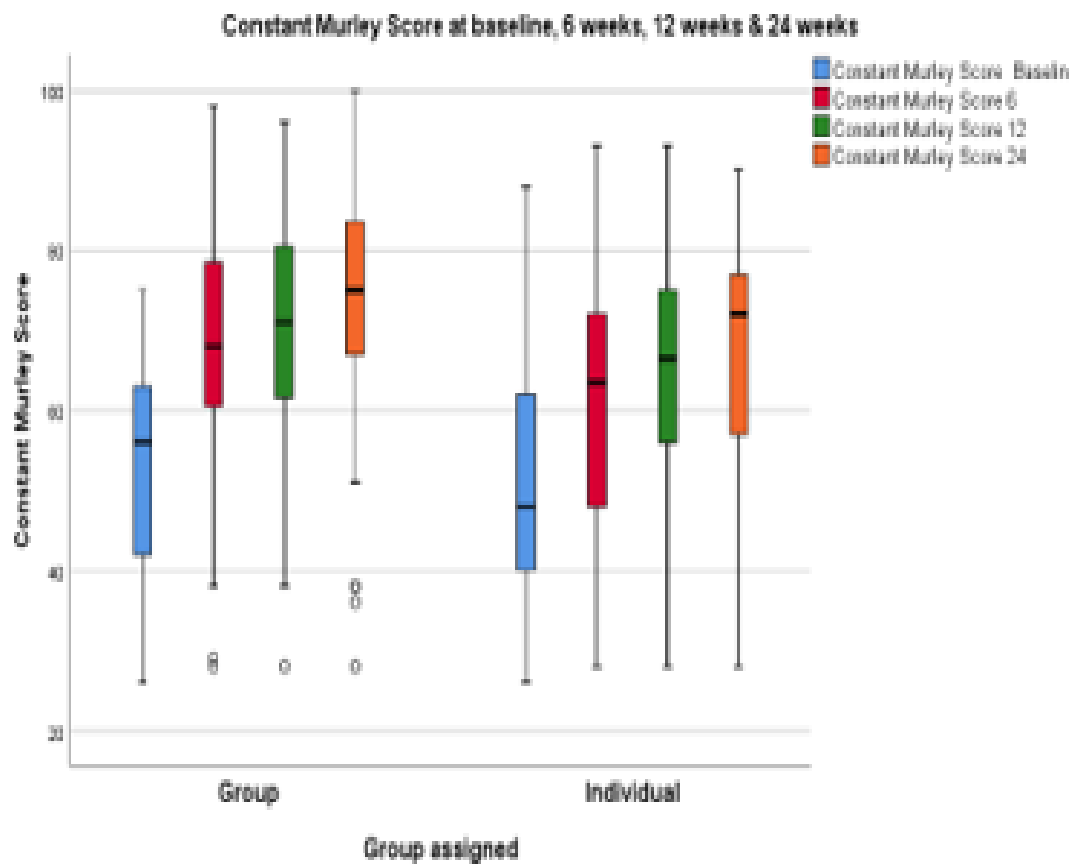
SPADI-Disability at baseline, 6 weeks, 12 weeks & 24 weeks



QuickDASH at baseline, 6 weeks, 12 weeks & 24 weeks







## Appendix N

COISTE EITICE UM THAIGHDE CLINICIÚIL

### Clinical Research Ethics Committee of the Cork Teaching Hospitals

Tel: +353-21-4901901

Email: [crec@ucc.ie](mailto:crec@ucc.ie)

University College Cork  
Lancaster Hall  
6 Little Hanover Street  
Cork  
Ireland

CREC Review Reference Number: ECM 4 (ii) 19/04/19

**Date:** 29<sup>th</sup> April 2019

Dr Mark Phelan  
Consultant Rheumatologist  
South Infirmary Victoria University Hospital  
Infirmary Road  
Cork

**Study Title:** Exploration of the experience of patients receiving either one to one physiotherapy or physiotherapy-led group exercise for the treatment of shoulder pain (rotator cuff tendinopathy) in Primary Care.

Approval is granted to carry out the above study at:

South Lee Primary Care.

The following documents have been approved:

Document	Approved	Version	Date
Cover Letter			
Application Form	Yes		5 <sup>th</sup> April 2019 (Received 9 <sup>th</sup> April 2019)
CV for Chief Investigator	Yes		
Evidence of Insurance	Yes		
Study Protocol			
Data Collection Sheet			
Participant Information Leaflet	Yes		
Consent Form	Yes		Add researcher signature section prior to use
Study Questionnaire/Survey			
Interview Guide	Yes		

We note that the co-investigator(s) involved in this project will be:

Name	Occupation
Deirdre Kiely	Senior Physiotherapist
Karen McCreesh	Senior Lecturer
Rose Galvin	Senior Lecturer
Christina O'Connor	PhD Candidate.

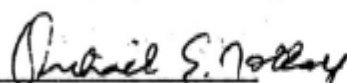
Please note that the above study must be carried out in accordance with GDPR 2018.

Keep a copy of this signed approval letter in your study master file for audit purposes.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter)
2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study
3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.
4. Notify CREC of discontinuation of the study
5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely



Professor Michael G Molloy  
Chairman  
Clinical Research Ethics Committee  
of the Cork Teaching Hospitals

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*The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.*

## Appendix O



### CONSENT BY SUBJECT FOR PARTICIPATION IN A RESEARCH STUDY

Exploration of the experience of patients receiving either one to one physiotherapy or physiotherapy-led group exercise for the treatment of shoulder pain (rotator cuff tendinopathy) in Primary Care.

**Chief Investigator:** Dr Mark Phelan, Consultant Rheumatologist, South Infirmary Victoria University Hospital.

**Study Co-Investigators:** Deirdre Kiely (Senior Physiotherapist, HSE), Karen McGeehan (Senior Lecturer University of Limerick), Rose Galvin (Senior Lecturer University of Limerick, Christina O' Connor (PhD candidate, University of Limerick).

**This Informed Consent Form has two parts:**

- Participants information leaflet (to share information about the research with you).
- Certificate of Consent (for your signature if you agree to take part).

**You will be given a copy of the Informed Consent Form, if you wish.**

#### **PART 1: Participants Information Leaflet**

##### **Purpose of the research**

The purpose of this research is to explore the experience of patients who have received treatment for shoulder pain in either a physiotherapist-led group exercise class or in individual physiotherapy sessions. The aim is to identify any preferences for either group or one to one physiotherapy, satisfaction with the treatment received, ability to manage your shoulder problem and adherence to your home exercise programme.

##### **Type of research intervention**

Taking part in this study involves engaging in a private telephone interview with a researcher about your experience of the treatment you have received for your shoulder problem.

##### **Participant selection**

You are invited to take part in the this research study as you have completed physiotherapy treatment for your shoulder problem at Blackrock Hall Physiotherapy Department in either a physiotherapist-led group exercise class or in individual physiotherapy sessions

##### **Voluntary participation**

Taking part in this study is voluntary and you are free to refuse to participate. You can withdraw from the study at any time without any consequence. No questions will be asked.

### **Nature and Duration of Procedure**

Taking part in this study involves engaging in a private telephone interview with a researcher at a time which is convenient for you. The interview will last up to 30 minutes. The interview will be recorded with a Dictaphone. A brief summary will be sent to you, via post or email, to ensure that you are satisfied that the transcription is an accurate reflection of your comments within the interview situation.

### **Risks and Benefits**

There are no risks involved with taking part in this study. If you decide to participate, you will not benefit directly from taking part in this study. However the information we will obtain may provide us with additional insight into the treatment preferences and positives or negatives of these two types of treatment, for people with this type of shoulder problem.

### **Confidentiality**

All of the information that you provide, as part of the research study, will be kept confidential at all times. Direct quotations relating to your response to interview questions may be used in publications or presentations. However, your actual name will not be used within the quotation and any identifying information will not be reported in any forum/literature arising from this research. Your data, transcripts of interviews and recordings, will be stored in a locked cupboard in the physiotherapy department at Blackrock Hall primary care centre for 7 years. They will then be destroyed.

### **Reimbursements**

There is no financial compensation for participation.

### **Ethical approval**

University College Cork's Clinical Research Ethics Committee have reviewed and approved this study.

### **Who to contact:**

If you have any questions about the study, you may contact either of the researchers listed below. It is important that you feel that all of your questions have been answered.

Deirdre Kiely, PCC Physiotherapy Department, 2<sup>nd</sup> Floor, Carrigaline Primary Care Centre, Estuary Business & Technology Park, Kilnagleary, Carrigaline, Co. Cork.  
Telephone: 021-4540203.

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## PART II: Certificate of Consent

1. I confirm that I have received a copy of the Information for Participants Leaflet for the above study. I have read it and I understand it. I have received an explanation of the nature, purpose, duration of the study and what my involvement will be.
2. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without consequence and without giving any reason.
4. I agree to allow my interview to be audio-recorded.
5. I agree to take part in this study.                      Yes ☐                      No ☐

Print Name of Participant \_\_\_\_\_

Signature of Participant \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year

Please return this consent form in the stamped addressed envelope provided or return to:

Deirdre Kiely, PCC Physiotherapy Department, 2<sup>nd</sup> Floor, ~~Carrigaline~~ Primary Care Centre, Estuary Business & Technology Park, ~~Kilnagleary, Carrigaline~~, Co. Cork

## **Appendix P**

### **PROTOCOL**

**Exploration of the experience of patients receiving either one to one physiotherapy or physiotherapy-led group exercise for the treatment of shoulder pain (rotator cuff tendinopathy) in Primary Care.**

#### **Background/Rationale**

Shoulder pain is the third most common musculoskeletal (MSK) disorder seen in primary care physiotherapy (May 2003). Almost 40% of shoulder patients have pain that lasts greater than one year (Winters *et al.* 1999). It has a huge impact on quality of life and is associated with high levels of psychological co-morbidity (Gartsman *et al.* 1998).

Primary care physiotherapists are often the first healthcare professionals to provide treatment and see the whole spectrum of shoulder pain patients from acute to very chronic. A systematic review and meta-analysis by (O'Keeffe *et al.* 2017) found similar outcomes for patients with MSK conditions who were treated in groups as compared to 1:1 physiotherapy. This may also be a more cost effective way of treating these patients. We have recently been involved in conducting a single-blinded randomised trial, comparing the effectiveness, on pain and disability, of a physiotherapy-led group exercise intervention with 1:1 usual care physiotherapy for patients with rotator cuff tendinopathy in primary care. The trial has finished and the data is now undergoing analysis. However, if group exercise interventions are as or more effective than 1:1 physiotherapy for this population, it makes sense that most patients seen in primary care should be treated in this way. Nevertheless, patient choice must also be considered. As physiotherapists, we may have a preconceived notion that patients expect one to one physiotherapy and will be disappointed if offered treatment in a group.

Qualitative research on physiotherapy-led group exercise interventions for shoulder pain has shown that the majority of patients who participated in a group expressed a preference for it compared with one to one physiotherapy, deriving benefit from the social interaction of a group and valuing the repeated practice allowed by a weekly group (Barrett *et al.* 2018). Others report that adherence to exercise programmes may be superior amongst patients attending a class compared with those performing home exercise programmes (Abramson 2018). In this study, we propose to interview participants from both arms of the randomised interventional trial.

#### **Aim**

The aim is to explore the experiences of patients receiving either group based or individual treatment for their shoulder pain condition, in relation to their treatment preference, adherence, and satisfaction.

#### **Methods**

##### **Study Design**

A qualitative study using semi-structured interviews.

## **Participants**

Participants will have a history of rotator cuff tendinopathy and were referred to primary care physiotherapy in Blackrock Hall primary care centre.

## **Recruitment**

Eligible participants will be contacted by phone by a researcher. The researcher will explain what the research entails and will invite them to participate. Eligible participants who are interested in participating will be sent a participant information leaflet and a consent form along with a stamped addressed envelope. They will be asked to return the signed consent form by post. Once the consent form has been received, the researcher will contact participants and schedule their interview for a convenient time.

## **Data Collection Procedures**

Data collection will be via semi-structures interviews. Interviews will be by telephone. Fully informed written consent will be obtained from all participants prior to data collection. A semi-structured topic guide will be developed to guide the interviews. Interviews will last approximately 30 minutes. Interviews will be recorded using a Dictaphone and transcribed verbatim. The transcripts will be verified by the participants through post or email. Transcripts and recordings of interviews will be kept in a locked cupboard at the physiotherapy department at Blackrock Hall primary care centre for a period of 7 years. They will then be destroyed.

## **Data Analysis**

Interviews will be transcribed verbatim by a physiotherapy student. The data will be analysed using inductive thematic analysis, to identify common themes within and between participants.

## **Probable duration of protocol**

3 months

## **Location**

South Lee Primary Care, Cork

## **Special Precautions**

This study does not involve an intervention but does involve collection of additional information from patients via interviews. These interviews will be carried out at a time convenient for the participant by telephone. It will be made very clear to participants that they are under no obligation to participate.

## **Type and number of subjects**



Participants will have a history of rotator cuff tendinopathy, were referred to primary care physiotherapy in Blackrock Hall primary care centre and have completed their treatment will be eligible for the trial. It is estimated that 10 participants will be recruited.

### **Potential risks and benefits**

There are no risks to participants. There will be no direct benefit to the participants of this study. Results of this study will explore patients' perceptions of the treatment they received for their rotator cuff tendinopathy in either a physiotherapy-led group or in individual physiotherapy sessions, their satisfaction with same, their preference for either 1:1 treatment or group exercise, their understanding of their condition and therefore ability to manage it, any barriers to participating in a group, their adherence to their home exercise programme and their confidence in performing same. It is hoped that the results will lead to a better understanding of patients' feelings about group and individual treatment and whether group exercise is an acceptable alternative to traditional 1:1 treatment for this patient group. It is also hoped that it will lead to a better understanding factors affecting adherence to home exercise programmes and the efficacy of delivering education in a group or 1:1.

### **Procedures to obtain informed consent**

Eligible subjects will be contacted by a researcher by telephone and invited to participate in the trial, a telephone interview. Interested subjects will be sent a Participant Information leaflet, a consent form and a stamped addressed envelope. It will be necessary for a signed consent form to be returned prior to study enrolment. The researcher will contact participants a second time to check the participants' willingness to proceed and they will be given the opportunity to ask further questions. A convenient time for the telephone interview will then be scheduled.

## Topic guide

**Intro:** Thank you for taking part in this study. I am a researcher from University of Limerick. I am going to talk to you about the physiotherapy treatment that you received in Blackrock Hall for your shoulder problem last year. We are interested in finding out about people's treatment preferences and their experience of the treatment they have received for their shoulder pain. This will help us to plan how we deliver treatment to other patients with shoulder problems. This should take about 15 – 20 minutes.

1. When you took part in the study last year, you weren't allowed to choose whether you received individual treatment sessions or treatment or treatment in the exercise class. How did you feel about getting this treatment versus the other treatment?

- Has your opinion changed?
- Having completed your treatment, do you think you would have benefitted more from receiving the other treatment?

2. Do you feel that the treatment you received has benefitted your shoulder?

- Did you feel that you got enough individual time? (group)
- Do you feel like you received enough treatment (individual)? Would you have liked the treatment to continue?

3. What are the positives/benefits of individual/group treatment?

- Are there any negatives/challenges to being in a group/receiving individual treatment?

4. Did you receive any education about your shoulder condition?

- What did you find useful?
- What is your understanding of your shoulder problem?

5. Have you continued with your home exercises?

- If so, what has helped (e.g. booklet, printed HEP)
- How confident are you that you are performing them correctly?
- Do you feel they are improving your shoulder condition?

6. How confident are you that you can manage your shoulder problem independently if it did give you trouble again?

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